VIVUS INC
Form 10-K
March 13, 2006

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

ý **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2005

OR

o **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 (NO FEE REQUIRED)**

For the transition period from to

Commission File Number 0-23490

VIVUS, INC.

(Exact name of Registrant as specified in its charter)

Delaware	**94-3136179**
(State or other jurisdiction of incorporation or organization)	(IRS employer identification number)
1172 Castro Street Mountain View, California	**94040**
(Address of principal executive office)	(Zip Code)

Registrant s telephone number, including area code: **(650) 934-5200**

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	**Name of Each Exchange on Which Registered**
None	

Securities registered pursuant to Section 12(g) of the Act:

Common Stock, $.001 Par Value

(Title of class)

Preferred Share Purchase Rights

(Title of class)

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ý No o

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ý No o

Note- checking the box above will not relieve any registrant required to file reports pursuant to Section 13 of 15(d) of the Exchange Act from their obligations under those Sections.

Indicate by check mark whether the Registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ý No o

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of Registrant s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. o

Indicate by check mark whether the Registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer o Accelerated filer ý Non-accelerated filer o

Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Act). o Yes ý No

The aggregate market value of the common equity held by non-affiliates of the Registrant as of June 30, 2005 totaled approximately $164,300,279 based on the closing stock price as reported by the Nasdaq National Market.

As of February 24, 2006, there were 44,641,591 shares of the Registrant s Common Stock, $0.001 par value per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Document Description	**10-K part**
Portions of the Registrant s notice of annual meeting of stockholders and proxy statement to be filed pursuant to Regulation 14A within 120 days after Registrant s fiscal year end of December 31, 2005 are incorporated by reference into Part III of this report.	III, ITEMS 10, 11, 12, 13, 14

VIVUS, INC.

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PART I

FORWARD LOOKING STATEMENTS

This Form 10-K contains forward-looking statements that involve risks and uncertainties. These statements typically may be identified by the use of forward-looking words or phrases such as believe, expect, intend, anticipate, should, planned, estimated, and potential, among others. All forward-looking statements included in this document are based on our current expectations, and we assume no obligation to update any such forward-looking statements. The Private Securities Litigation Reform Act of 1995 provides a safe harbor for such forward-looking statements. In order to comply with the terms of the safe harbor, we note that a variety of factors could cause actual results and experiences to differ materially from the anticipated results or other expectations expressed in such forward-looking statements. The risks and uncertainties that may affect the operations, performance, development, and results of our business include but are not limited to: (1) our history of losses and variable quarterly results; (2) substantial competition; (3) risks related to the clinical trial development of products not yet approved; (4) our reliance on sole source suppliers; (5) our limited sales and marketing efforts and our reliance on third parties; (6) failure to continue to develop innovative products; (7) risks related to noncompliance with United States Food and Drug Administration regulations; (8) risks related to the failure to protect our intellectual property and litigation in which we may become involved; and (9) other factors that are described from time to time in our periodic filings with the Securities and Exchange Commission, including those set forth in this filing as Item 1A. Risk Factors.

Item 1. ***Business***

Overview

VIVUS, Inc. is a specialty pharmaceutical company focused on the research, development and commercialization of products to restore sexual function in women and men. Our product pipeline includes four clinical stage product candidates, each of which targets an estimated existing or potential market in excess of $1 billion annually. Evamist™, currently in Phase 3 development, is our product candidate to alleviate symptoms associated with menopause. Avanafil, which recently completed Phase 2 trials, is our phosphodiesterase type 5, or PDE5, inhibitor product candidate for the treatment of erectile dysfunction. ALISTA™, currently in Phase 2B trials, is our product candidate for the treatment of female sexual arousal disorder (FSAD). Testosterone MDTS®, which has completed a positive Phase 2 trial, is our product candidate to treat hypoactive sexual desire disorder (HSDD).

In 1997, we launched MUSE® (alprostadil) in the United States and, together with our partners in 1998, internationally. We market MUSE as a prescription product for the treatment of erectile dysfunction. For international markets, we have entered into supply and distribution agreements with established pharmaceutical companies to market and distribute MUSE in various foreign countries. MUSE was the first minimally invasive therapy for erectile dysfunction available at a time when only more invasive therapies existed. Developing and bringing MUSE to the market provided us with experience in clinical and regulatory matters when the market for erectile dysfunction was in its infancy.

We have funded operations primarily through private and public offerings of our common stock and through product sales. We expect to generate future net losses due to increases in operating expenses as product candidates are advanced through the various stages of clinical development. As of December 31, 2005, we have incurred a cumulative deficit of $147.0 million and expect to incur operating losses in the near

future.

Our Product Pipeline

We currently have four research and development programs targeting female and male sexual health:

Product	Indication	Status	Patent Expiry and Number
Evamist (Estradiol-MDTS)	Menopausal symptoms	Phase 3 ongoing	2017 (US 6,818,226)
ALISTA (topical alprostadil)	Female sexual arousal disorder (FSAD)	Phase 2B ongoing	2017 (US 5,877,216)
Testosterone MDTS	Hypoactive sexual desire disorder (HSDD)	Phase 2 completed	2017 (US 6,818,226)
Avanafil (PDE5 inhibitor)	Erectile dysfunction (ED)	Phase 2 completed	2020 (US 6,656,935)

Female Sexual Health

We believe the market for the treatment of female sexual health is large and underserved. Issues related to female sexual health include sexual disorders, such as FSAD and HSDD, as well as vasomotor symptoms associated with menopause. A paper published in the *Journal of the American Medical Association* in 1999 noted that 43% of women between the ages of 18 and 59 identified themselves as afflicted with a sexual disorder, reporting female sexual arousal disorder and hypoactive sexual desire disorder as the

two most common conditions of female sexual dysfunction, or FSD. Currently, there are no pharmaceutical treatments on the market that have been approved by the United States Food and Drug Administration, or the FDA, for the treatment of these sexual disorders in women.

Evamist

Menopausal Vasomotor Symptoms

Vasomotor symptoms such as hot flashes and vaginal atrophy are reported to be among the most common medical complaints of women going through menopause. Each year an estimated 1.5 million women in the United States enter menopause. As many as 75% of menopausal women experience vasomotor symptoms at some time during menopause, although the frequency and severity may vary. The cause of vasomotor symptoms is related to a decrease in estrogen production by the ovaries that accompanies menopause. As a result, temperature regulation is altered, resulting in increased vasodilation of skin blood vessels and feelings of hot flashes and sweating. Estrogen and estradiol products are generally considered to be highly effective treatments for menopausal vasomotor symptoms. Sales of estrogen products in the United States in 2005 were estimated to be $1.5 billion.

Premarin®, an oral preparation of conjugated estrogens, is the most widely prescribed estrogen therapy in the United States. In 2004, a long-term, large-scale study that evaluated the effects of Premarin was terminated by the National Institutes of Health. This study, called the Women s Health Initiative (WHI), demonstrated an increase in the number of strokes and deep vein thromboses in women receiving Premarin as compared to placebo. This finding may be explained by previously published studies, which showed that when given orally, conjugated equine estrogens are associated with potentially deleterious changes in triglycerides, inflammatory mediators, and certain clotting factors. We believe that these changes may be the result of the liver s metabolism of oral conjugated equine estrogens.

In contrast to orally administered conjugated estrogens, the use of transdermal estradiol, which avoids first pass metabolism by the liver, has been shown in studies to result in little or no significant changes in triglycerides, inflammatory mediators or clotting factors. Therefore, we believe transdermal estradiol may offer a safer means of treating vasomotor symptoms associated with menopause.

A recently published study, called the Nurses Health Study involving over 120,000 women, suggested that initiating hormone therapy at the onset of menopause resulted in an approximate 30% reduction in the risk of coronary heart disease compared to women who never used hormones. These results support that early initiation of hormone therapy in relation to the onset of menopause might have a positive influence on reducing the risk of coronary heart disease in women.

Our Clinical Candidate

Evamist is our patented estradiol spray being developed for the treatment of vasomotor symptoms associated with menopause. Evamist uses our proprietary, metered-dose transdermal spray, or MDTS, applicator that delivers a precise amount of estradiol to the skin. We believe that the MDTS technology has significant advantages over patches and gels. The applied dose dries in approximately 60 seconds. It is not messy. It is easy to apply and becomes invisible. We licensed the U.S. rights for this product from Acrux Limited (Acrux) in 2004. Acrux s studies have demonstrated that the Estradiol-MDTS system delivers sustained levels of estradiol in women over a 24-hour period. We have also completed various additional studies with Evamist to measure the effects of washing, transfer and the application of sunscreen.

Clinical Status

In December 2004, we initiated our Phase 3 study of Evamist in the United States to evaluate its safety and efficacy in menopausal women suffering from vasomotor symptoms. We received a Special Protocol Assessment (SPA) from the FDA, which is an official agreement that documents the agreed upon terms and conditions under which we will conduct and analyze the data from our Phase 3 trial. The primary endpoint is to assess the decrease in the frequency and severity of hot flashes at 4 and 12 weeks of treatment. In September 2005, we completed enrollment for this trial. Results from this study are expected in the second quarter of 2006. Assuming favorable study results, we anticipate submitting the New Drug Application (NDA) for Evamist mid year 2006.

ALISTA

Female Sexual Arousal Disorder

FSAD, the persistent or recurrent inability to attain or maintain sufficient sexual excitement resulting in personal distress, has been reported to occur in 20 to 25% of women suffering from FSD. Sexual arousal in females involves vasodilation, or increased genital blood flow, which results in increased clitoral sensation and vaginal lubrication. Reduced vasodilation and lubrication resulting from atherosclerosis, diabetes and advancing age as well as surgeries such as hysterectomies can deleteriously affect a woman s ability to become sexually aroused.

There are no FDA-approved medical treatments for FSAD.

Our Clinical Candidate

ALISTA is a patented formulation of alprostadil that is intended for topical application to the female genitalia prior to sexual activity as an on-demand treatment for FSAD. ALISTA has been designed to increase blood flow in the genital region, allowing for greater sensitivity and sexual arousal. These positive effects have been observed as early as 5 to 15 minutes after application of ALISTA and may last up to two hours.

The active ingredient in ALISTA, alprostadil, is a synthetic version of a naturally occurring molecule found in humans. Alprostadil has been approved by the FDA for other indications, including erectile dysfunction in men. We believe the combination of alprostadil s ability to achieve vasodilation in genital tissues, its long-standing safety record, and short half-life makes it an ideal agent for the treatment of FSAD.

Clinical Status

We have completed three double-blind, randomized, placebo-controlled Phase 2 studies of ALISTA, all of which demonstrated statistically significant increases in arousal and/or satisfying sexual encounters in pre- and post-menopausal women with FSAD. One of these studies was a double-blind, placebo-controlled, crossover-design trial to evaluate the response to ALISTA administered at home by 51 women. The study showed that 64 percent of ALISTA doses resulted in Satisfactory Sexual Events (SSEs) and the use of ALISTA also resulted in significant improvement in orgasm. This was the first trial that evaluated the use of ALISTA in premenopausal women in the home setting. No serious adverse events were reported during this study.

We initiated a clinical trial of ALISTA in 2004 in post-menopausal women with FSAD. In mid 2004 the FDA revised the guidance on the endpoints necessary for approval of products to treat FSAD. The primary endpoint of the current study is the increase in the number of SSEs per month during the 24-week treatment period relative to the initial 8-week baseline period. The trial will also measure changes in arousal and distress associated with the patients FSAD; however the trial was not designed for co-primary endpoints. Over 300 women who have undergone a hysterectomy and who have been diagnosed with FSAD were enrolled at 45 centers throughout the United States. In December 2005, we announced that we had completed enrollment in this multi-center, randomized, double blind, placebo-controlled Phase 2B study. Patients are expected to complete the trial late in 2006. Our development plan for ALISTA calls for subsequent large-scale confirmatory studies following completion of the current clinical trial. For regulatory approval, the FDA now requires co-primary endpoints that must include statistically significant increases in both the number of SSEs and improvement in the self-assessed level of sexual arousal using validated questionnaires.

Testosterone MDTS

Hypoactive Sexual Desire Disorder

Hypoactive sexual desire disorder, the persistent or recurrent lack of interest in sexual activity resulting in personal distress, is reported to be the most common type of female sexual dysfunction, affecting as many as 30% of women in the United States. Several studies over the last several decades have demonstrated that testosterone is an important component of female sexual desire. As a woman ages, there is a decline in testosterone production. The administration of testosterone has been associated with an increase in sexual desire in both pre- and post-menopausal women. In addition to the gradual decline in testosterone that accompanies aging and natural menopause, the surgical removal of a woman s ovaries rapidly results in a decrease of approximately one half of the woman s testosterone production capability. Hence, HSDD can

occur much faster, and at a younger age, in women who have undergone this type of surgically induced menopause. Furthermore, HSDD has been observed in pre-menopausal women with naturally occurring low levels of testosterone.

There are no FDA-approved medical treatments for HSDD.

Double-blind, multicenter, placebo-controlled clinical trials conducted by The Procter & Gamble Company to assess the effects of a twice-weekly testosterone patch demonstrated a statistically significant increase in the number of satisfying sexual events in surgically induced menopausal women. In addition, an independent clinical study demonstrated that transdermally applied testosterone has the ability to improve sexual desire in pre-menopausal women with HSDD.

Our Clinical Candidate

Testosterone MDTS is our patent protected, transdermal product for the treatment of HSDD in women. The active ingredient in Testosterone MDTS is the synthetic version of the testosterone that is present naturally in women and men.

Testosterone MDTS utilizes a proprietary, metered-dose transdermal spray, or MDTS, applicator that delivers a precise amount of testosterone to the skin. We licensed the U.S. rights for this product from Acrux Limited in 2004. The metered spray enables patients to apply a precise dose of testosterone for transdermal delivery. The applied dose dries in approximately 60 seconds and becomes invisible. Acrux s studies have demonstrated that the Testosterone MDTS system delivers sustained levels of testosterone in women over a 24-hour period, achieves efficacy in increasing the number of satisfying sexual events, and results in substantially lower rates of application site skin irritation than reported in women using testosterone patches.

We believe that our Testosterone MDTS product has significant advantages over patches and other transdermal gels that are being developed for this indication. The Testosterone MDTS spray allows for discreet application, unlike patches that are visible and topical gels that are messy. We believe that the patented MDTS delivery technology will prevent others from commercializing competitive therapies utilizing a spray delivery technology.

Clinical Status

In February 2005, we announced along with Acrux, positive Phase 2 results for Testosterone MDTS, which showed a statistically significant improvement in the number of satisfying sexual events in pre-menopausal patients with hypoactive sexual desire disorder.

Earlier clinical trials to assess the MDTS technology were conducted by Acrux. These studies demonstrated that application of Testosterone MDTS to the skin resulted in absorption of predictable amounts of testosterone. The amount absorbed was comparable to that absorbed on a daily basis from the Procter and Gamble transdermal testosterone patch that was shown in Phase 3 trials to improve sexual desire in women with HSDD.

In September 2005, we met with the FDA to share results from our Phase 2 clinical study and to discuss the Phase 3 study requirements for obtaining approval for this indication. Although final Phase 3 protocols have not been agreed upon, the FDA provided guidance to us on the size of and endpoints for the Phase 3 program. Based on the meeting and the discussions with the FDA, we intend to complete the design of the Phase 3 safety and efficacy studies for the use of Testosterone MDTS to treat HSDD over the next several months. We intend to obtain a Special Protocol Assessment (SPA) for the pivotal safety and efficacy studies prior to their initiation.

Male Sexual Health

Erectile dysfunction (ED), or the inability to attain or maintain an erection sufficient for intercourse, was reported by 35% of men between the ages of 40 to 70 in the United States, according to an independent study, with the incidence increasing with age. ED, frequently associated with

vascular problems, is particularly common in men with diabetes and in those who have had a radical prostatectomy for prostate cancer. PDE5 inhibitors such as sildenafil (Viagra®), vardenafil (Levitra®) and tadalafil (Cialis®), which inhibit the breakdown of cyclic guanosine monophosphate, have been shown to be effective treatments for ED.

The worldwide sales in 2005 of PDE5 inhibitor products for ED were in excess of $ 2.7 billion, including approximately $1.6 billion in sales of Viagra, approximately $747 million in sales of Cialis and approximately $313 million in sales of Levitra. Based on the aging baby boomer population and the desire to maintain an active sexual lifestyle, we believe the market for PDE5 inhibitors will continue to grow.

Avanafil

Our Clinical Candidate

We are developing avanafil, an orally administered PDE5 inhibitor, which we licensed from Tanabe Seiyaku Co., Ltd., or Tanabe, in 2001. We have exclusive worldwide development and commercialization rights for avanafil with the exception of certain Asian markets.

Pre-clinical and clinical data suggests that avanafil:

- is highly selective to PDE5, which we believe may result in a favorable side effect profile;
- has a shorter plasma half-life than currently approved PDE5 inhibitors; and
- is fast-acting.

While PDE5 inhibitors currently on the market are often effective in treating ED, newer drugs that possess better specificity for the PDE5 enzyme may be safer. In addition to PDE5, there are at least ten other types of PDE enzymes in the human body. Drugs that inhibit more than one of these enzymes can potentially cause significant adverse effects, depending on the enzymes that are affected. In an in vitro study conducted by Tanabe comparing the activity of avanafil, sildenafil, tadalafil and vardenafil against all 11 of the known PDE enzymes, Tanabe found that avanafil demonstrated the best specificity for PDE5, with little activity against the other enzymes.

Avanafil possesses a shorter plasma half-life than other PDE5 inhibitors currently on the market. The plasma half-life of a drug is the amount of time required for 50% of the drug to be removed from the bloodstream. In general, the shorter the half-life, the less potential there is for the drug to interact with other drugs that may also be in the bloodstream. All approved PDE5 inhibitors are required by the FDA to include warnings against taking nitrates after administration. For example, Cialis s label warns patients not to take nitrates within 48 hours of administration. Approximately 5.5 million men take nitrates on a regular basis for angina pectoris and another half million annually will experience a heart attack and are potential candidates for emergency nitrate therapy. Sildenafil and vardenafil possess plasma half-lives of approximately four hours, and tadalafil has an extended half-life of 17 to 18 hours. The plasma half-life of avanafil, however, is approximately 90 minutes, which means that it is removed from the bloodstream faster than the other currently available PDE5 inhibitors. We believe avanafil s short half-life, high specificity and fast onset of action are ideal characteristics for an on-demand treatment for ED.

Clinical Status

We have conducted a number of clinical trials with avanafil, including pharmacokinetic and in-clinic studies as well as at-home efficacy trials in men with ED.

In June 2005, we announced positive results from a Phase 2, multicenter, double-blind, randomized, parallel-design study conducted to assess the safety and efficacy of different doses of avanafil for the treatment of ED. Patients in this study were instructed to attempt sexual intercourse 30 minutes after taking avanafil, with no restrictions on food or alcohol consumption. Results showed that up to 84% of avanafil doses resulted in erections sufficient for vaginal penetration, as compared to those who received a dosage of placebo. No serious adverse events were reported during this study.

In May 2005, we released the results from an open-label, pharmacokinetic study designed to evaluate the feasibility of allowing avanafil to be taken twice in a 24-hour period. This study compared blood levels of avanafil in healthy volunteer subjects after taking a single dose of avanafil and after taking avanafil every 12 hours for seven days. The results showed no significant plasma accumulation of avanafil after the twice-a-day treatment regimen when compared to the single dose.

In April 2005, the results of a clinical pharmacology study conducted to evaluate the hemodynamic responses (blood pressure and heart rate) to glyceryl trinitrate (GTN) in subjects pretreated with placebo, avanafil, and sildenafil citrate (Viagra) were announced. Results revealed that avanafil had less impact on blood pressure and heart rate than Viagra.

An End-of-Phase 2 meeting with the FDA for avanafil took place in November 2005. We discussed the Phase 2 results and the proposed protocol for the Phase 3 trials. Based on this meeting, we will proceed with finalizing the Phase 3 protocol and it is our intention to request a Special Protocol Assessment from the FDA prior to the initiation of the pivotal Phase 3 trials.

Our Marketed Product

MUSE

In 1997, we commercially launched MUSE in the United States. MUSE was the first minimally invasive therapy for erectile dysfunction approved by the FDA. With MUSE, an erection is typically produced within 15 minutes of administration and lasts approximately 30 to 60 minutes. Alprostadil is the active pharmacologic agent used in MUSE. Alprostadil is the generic name for the synthetic version of prostaglandin E1, a naturally-occurring vasodilator present in the human body and at high levels in seminal fluid.

MUSE is designed to overcome the limitations of other available therapies through its unique product attributes. Because therapeutic levels of drug are delivered locally to the erectile tissues with minimal systemic drug exposure, MUSE is a relatively safe, local treatment that minimizes the chances of systemic interactions with other drugs or diseases. Because it mimics the normal vasoactive process, MUSE produces an erection that is more natural than those resulting from needle injection therapy, vacuum constriction devices or penile implants. Over 11 million units of MUSE have been sold since we introduced MUSE to the market.

In May 2005, results were reported from a study, conducted by the Cleveland Clinic which focused on an individual s ability to restore sexual function following radical prostatectomy, a common treatment for prostate cancer. The study showed that 74% of patients who completed six months of MUSE treatment were able to resume sexual activity and 39% were able to achieve natural erections sufficient for intercourse without the use of erectogenic agents.

Other Programs

We have licensed and intend to continue to license from third parties the rights to other products to treat various sexual and nonsexual disorders. We also sponsor early stage clinical trials at various research institutions. We expect to continue to use our expertise in designing clinical trials, formulation and product development to commercialize pharmaceuticals for unmet medical needs or for disease states that are underserved by currently approved products. We intend to develop products with a proprietary position or that complement our other products currently under development. At the present time one of these products, outside the area of sexual dysfunction, is being considered for further development. Initial development plans include working with the FDA on the design of additional studies, prosecuting filed and pending patents and developing a formulation. Depending on the outcome of these activities we may allocate certain resources towards this program. However there can be no assurance that we will be successful with any or all of these activities or that we will pursue the development of this program at all.

Government Regulations

FDA Regulation

Prescription pharmaceutical products are subject to extensive pre- and post-marketing regulation by the FDA, including regulations that govern the testing, manufacturing, safety, efficacy, labeling, storage, record-keeping, advertising and promotion of the products under the Federal Food, Drug and Cosmetic Act and the Public Health Services Act, and by comparable agencies in most foreign countries. The process required by the FDA before a new drug may be marketed in the U.S. generally involves the following: completion of pre-clinical laboratory and animal testing; submission of an investigational new drug application, or IND, which must become effective before clinical trials may begin; performance of adequate and well controlled human clinical trials to establish the safety and efficacy of the proposed drug s intended use; and approval by the FDA of an NDA.

The activities required before a pharmaceutical agent may be marketed in the United States begin with pre-clinical testing.
Pre-clinical tests include laboratory evaluation of potential products and animal studies to assess the potential safety and efficacy of the product and its formulations. The results of these studies and other information must be submitted to the FDA as part of an IND application, which must be reviewed and approved by the FDA before proposed clinical testing can begin. Clinical trials involve the administration of the investigational new drug to healthy volunteers or to patients under the supervision of a qualified principal investigator. Clinical trials are conducted in accordance with Good Clinical Practices under protocols that detail the objectives of the study, the parameters to be used to monitor safety and the efficacy criteria to be evaluated. Each protocol must be submitted to the FDA as part of the IND application. Further, each clinical study must be conducted under the auspices of an independent institutional review board. The institutional review board will consider, among other things, ethical factors and the safety of human subjects.

Typically, human clinical trials are conducted in three phases that may overlap. In Phase 1, clinical trials are conducted with a small number of subjects to determine the early safety profile and pharmacology of the new therapy. In Phase 2, clinical trials are conducted with groups of patients afflicted with a specific disease in order to determine preliminary efficacy, optimal dosages and expanded evidence of safety. In Phase 3, large scale, multicenter, comparative clinical trials are conducted with patients afflicted with a target disease in order to provide enough data

for the statistical proof of efficacy and safety required by the FDA and others.

The results of the pre-clinical and clinical testing, together with chemistry and manufacturing information, are submitted to the FDA in the form of an NDA for a pharmaceutical product in order to obtain approval to commence commercial sales. In responding to an NDA, the FDA may grant marketing approvals, request additional information or further research, or deny the application if it determines that the application does not satisfy its regulatory approval criteria. Patient-specific therapies may be subject to additional risk with respect to the regulatory review process. FDA approval for a pharmaceutical product may not be granted on a timely basis, if at all, or if granted may not cover all the clinical indications for which approval is sought or may contain significant limitations in the form of warnings, precautions or contraindications with respect to conditions of use.

Satisfaction of FDA premarket approval requirements for new drugs typically takes several years, and the actual time required may vary substantially based upon the type, complexity and novelty of the product or targeted disease. Government regulation may delay or prevent marketing of potential products for a considerable period of time and impose costly procedures upon our activities. Success in early stage clinical trials or with prior versions of products does not assure success in later stage clinical trials. Data obtained from clinical activities are not always conclusive and may be susceptible to varying interpretations that could delay, limit or prevent regulatory approval.

Once approved, the FDA may withdraw the product approval if compliance with pre- and post-marketing regulatory standards is not maintained or if problems occur after the product reaches the marketplace. In addition, the FDA may require post-marketing studies, referred to as Phase 4 studies, to monitor the effect of an approved product, and may limit further marketing of the product based on the

results of these post-market studies. The FDA has broad post-market regulatory and enforcement powers, including the ability to levy fines and civil penalties, suspend or delay issuance of approvals, seize or recall products, or withdraw approvals.

Facilities used to manufacture drugs are subject to periodic inspection by the FDA, DEA and other authorities where applicable, and must comply with the FDA s cGMP regulations. Failure to comply with the statutory and regulatory requirements subjects the manufacturer to possible legal or regulatory action, such as suspension of manufacturing, seizure of product or voluntary recall of a product. Adverse experiences with the product must be reported to the FDA and could result in the imposition of market restriction through labeling changes or in product removal. Product approvals may be withdrawn if compliance with regulatory requirements is not maintained or if problems concerning safety or efficacy of the product occur following approval.

With respect to post-market product advertising and promotion, the FDA imposes a number of complex regulations on entities that advertise and promote pharmaceuticals, which include, among other things, standards and regulations relating to direct-to-consumer advertising, off-label promotion, industry sponsored scientific and educational activities, and promotional activities involving the Internet. The FDA has very broad enforcement authority under the Federal Food, Drug and Cosmetic Act, and failure to abide by these regulations can result in penalties including the issuance of a warning letter directing the entity to correct deviations from FDA standards, a requirement that future advertising and promotional materials be pre-cleared by the FDA, and state and federal civil and criminal investigations and prosecutions.

We are subject to various laws and regulations regarding laboratory practices, the experimental use of animals, and the use and disposal of hazardous or potentially hazardous substances in connection with our research. In each of these areas, as above, the government has broad regulatory and enforcement powers, including the ability to levy fines and civil penalties, suspend or delay issuance of approvals, seize or recall products, and withdraw approvals, any one or more of which could have a material adverse effect upon us.

Other Government Regulations

In addition to laws and regulations enforced by the FDA, we are also subject to regulation under National Institutes of Health guidelines, as well as under the Controlled Substances Act, the Occupational Safety and Health Act, the Environmental Protection Act, the Toxic Substances Control Act, the Resource Conservation and Recovery Act and other present and potential future federal, state or local laws and regulations, as our research and development involves the controlled use of hazardous materials, chemicals, viruses and various radioactive compounds.

In addition to regulations in the United States, we are subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of MUSE and our product candidates. Whether or not we obtain FDA approval for a product, we must obtain approval of a product by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. The approval process varies from country to country, and the time may be longer or shorter than that required for FDA approval. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country.

Corporate Collaborations and Licenses from Third Parties

Tanabe

In January 2001, we entered into an exclusive development, license and supply agreement with Tanabe for the development and commercialization of avanafil, a PDE5 inhibitor compound for the oral and local treatment of male and female sexual dysfunction. Tanabe is one of Japan s leading pharmaceutical companies with revenues of over $1.6 billion in 2004.

Under the terms of the agreement, Tanabe agreed to grant an exclusive license to us for products containing avanafil outside of Japan, North Korea, South Korea, China, Taiwan, Singapore, Indonesia, Malaysia, Thailand, Vietnam and the Philippines. We agreed to grant Tanabe an exclusive, royalty-free license within those countries for oral products that we develop containing avanafil. In addition, we agreed to grant Tanabe an exclusive option to obtain an exclusive, royalty-bearing license within those countries for non-oral products that we develop containing avanafil. Further, we granted Tanabe the option to obtain co-promotional rights for oral products that we develop under our license for up to 25% of the promotional activity in our territory. Tanabe agreed to manufacture and supply us with avanafil for use in clinical trials, which will be our primary responsibility.

We have paid upfront licensing fees to Tanabe and have agreed to make additional payments upon the completion of certain development, regulatory and sales milestones. We have further agreed to pay royalties on net sales of products containing avanafil. During the first quarter of 2004, we initiated a Phase 2 clinical trial with avanafil, which meets one of the milestone criteria above. We intend to pay Tanabe $2.0 million in connection with this milestone in March 2006.

In the first quarter of 2004, we also entered into a secured line of credit agreement with Tanabe Holding America, Inc., a subsidiary of Tanabe, allowing us to borrow up to $8.5 million to be used for the development of avanafil. We can draw upon the line of credit quarterly, with a 48-month term on each drawdown bearing 2% annual interest. We are not obligated under any financial covenants in connection with this agreement. As of December 31, 2005, we had long-term notes payable to Tanabe Holding America, Inc. of $5.2 million, and $3.3 million available for future borrowing.

Acrux

In February 2004, we entered into exclusive licensing agreements with Acrux Limited and a subsidiary of Acrux under which we have agreed to develop and commercialize Testosterone-MDTS and Evamist in the United States for various female health applications. Acrux s metered-dose transdermal spray, or MDTS, technology is a patented, simple to use spray that is being developed to deliver testosterone and estradiol effectively to women when applied to the skin. We agreed to grant Acrux s subsidiary a non-exclusive, royalty-free license outside the United States for any MDTS products containing improvements we have made to the licensed intellectual property and the option to obtain a non-exclusive, worldwide license for our intellectual property related to MDTS products.

Under the terms of the agreements, we agreed to pay to Acrux combined licensing fees of $3.0 million, up to $4.3 million for the achievement of certain clinical development milestones, up to $6.0 million for achieving product approval milestones, and royalties on net sales in the United States upon commercialization of each product.

Patents and Proprietary Technology

We hold 31 patents and 9 patent applications in the United States and related patents and patent applications in major foreign jurisdictions. We intend to develop, maintain and secure intellectual property rights and to aggressively defend and pursue new patents to expand upon our current patent base.

We have developed and acquired exclusive rights to patented technology in support of our development and commercialization of our products, and we rely on trade secrets and proprietary technologies in developing potential products. We continue to place significant emphasis on securing global intellectual property rights and are aggressively pursuing new patents to expand upon our strong foundation for commercializing products in development.

Manufacturing

We purchased our facilities, which we previously leased in Lakewood, New Jersey for our manufacturing operation, which includes formulation, filling, packaging, analytical laboratories, storage, distribution and administrative offices on December 22, 2005. The facility is cGMP certified and includes class 10,000 clean rooms used in the sterile production of MUSE. The facilities include two buildings totaling 90,000 square feet. The FDA and the Medicines and Healthcare products Regulatory Agency, the regulatory authority in the United Kingdom, authorized us to begin commercial production and shipment of MUSE from this facility in June and March 1998, respectively. We manufacture all of the worldwide demand for MUSE in this facility.

In addition to manufacturing, we have fully integrated manufacturing support systems including quality assurance, quality control and regulatory compliance. These support systems enable us to maintain high standards of quality for our products and simultaneously deliver reliable services and goods to our customers on a timely basis.

Sales and Marketing

We intend to market Evamist, if approved by the FDA, through an internal sales force calling on OB/GYN doctors, the primary prescribers of hormone therapies. We believe our direct marketing of Evamist will allow us to establish relationships with the OB/GYN physician community and to familiarize them with our MDTS technology in anticipation of Testosterone-MDTS entering the market. We intend to use these relationships to promote Testosterone-MDTS and ALISTA, our future product candidates in the female sexual health market.

For avanafil, we intend to enter into an agreement with a development and marketing partner that will provide commercial support for this primary care product, as well as financial support for future late-stage development activities. We intend to retain co-promotional rights and may use our existing specialty sales organization to market this product.

We anticipate that we will require additional funding to support internal sales and marketing efforts of our future products for which we do not have a marketing partner. We may seek to access the public or private equity markets whenever conditions are favorable. We may also seek additional funding through strategic alliances and other financing mechanisms. We cannot assure you that adequate funding will be available on terms acceptable to us, if at all. We cannot assure you that we will successfully market our products under development or that our products, if successfully marketed, will generate revenues sufficient to enable us to earn a profit.

We support MUSE sales in the United States with a direct sales team comprised of regional sales managers and telesales personnel calling on specialist physicians. We participate in national urologic and sexual dysfunction forums and conferences, such as the American Urological Association annual meeting and the International Society for Impotence Research.

We signed an international distribution agreement with Meda AB (Meda) in September 2002. According to the agreement, Meda will purchase MUSE from us for resale in member states of the European Union and certain other European countries. The agreement with Meda provides that Meda will earn a predetermined profit percentage on product sales. The transfer price at which we sell to Meda may change depending on the final price to the customer and the foreign exchange rate in the country where MUSE is sold. The current transfer price is in excess of the variable costs of manufacturing MUSE. Since our current facility is below maximum capacity, units sold to Meda contribute to reimbursement for the fixed costs of the manufacturing facilities. If the final selling price and/or the foreign exchange rate decreases, the gross profits on the sales of MUSE to Meda will decrease. In November 2000, we granted Paladin Labs the exclusive rights to distribute and market MUSE in Canada.

Competition

Competition in the pharmaceutical and medical products industries is intense and is characterized by extensive research efforts and rapid technological progress. Several large pharmaceutical companies are also actively engaged in the development of therapies for the treatment of female sexual dysfunction and male erectile dysfunction.

The most significant competitive therapy for MUSE is an oral medication marketed by Pfizer under the name Viagra, which received regulatory approvals in the United States in March 1998 and in the European Union in September 1998. The commercial launch of Viagra in the United States in April 1998 significantly decreased demand for MUSE. In February 2003, an oral medication under the name Cialis was launched in Europe by Lilly ICOS LLC and in Australia and New Zealand by Eli Lilly and Company alone. Lilly ICOS LLC launched Cialis in the United States in November 2003. Bayer AG and GlaxoSmithKline plc launched Levitra in the European Union in March 2003 and in the United States in September 2003.

Other treatments for erectile dysfunction exist, such as needle injection therapies, vacuum constriction devices and penile implants, and the manufacturers of these products will most likely continue to improve these therapies.

Several companies are developing products that could compete with our clinical candidates for the treatment of FSD.

NexMed, Inc. is developing Femprox, an alprostadil cream for the treatment of FSAD.

The Proctor & Gamble Company is developing a testosterone patch for the treatment of HSDD.

BioSante Pharmaceuticals, Inc. and others are developing forms of testosterone gels and creams for HSDD.

Palatin Technologies, Inc. and others are also developing various nasal sprays to treat FSD.

None of these products has been approved by the FDA.

Research and Development

We spent $17.0 million in 2005, $18.7 million in 2004, and $7.7 million in 2003 on research primarily to discover and develop our late-stage clinical products to restore sexual function in men and women, to license from third parties the rights to products to treat various sexual and nonsexual disorders and to sponsor early stage clinical trials at various research institutions.

Employees

As of February 28, 2006, we had 114 employees, including 80 of which are located at our manufacturing facility in Lakewood, New Jersey and 34 of which are located at our corporate headquarters in Mountain View, California and other United States locations. None of our current employees are represented by a labor union or are the subject of a collective bargaining agreement. We believe that we maintain good relations with our employees.

Insurance

We maintain product liability insurance for our currently marketed product, MUSE, and our clinical trials. Insurance coverage is becoming increasingly expensive, and no assurance can be given that we will be able to maintain insurance coverage at a reasonable

cost or in sufficient amounts to protect us against losses due to liability. There can also be no assurance that we will be able to obtain commercially reasonable product liability insurance for any products approved for marketing.

International Operations

We entered into an agreement granting Meda AB exclusive marketing and distribution rights for MUSE in member states of the European Union, the Baltic States, the Czech Republic, Hungary, Iceland, Norway, Poland, Switzerland and Turkey and we entered into an agreement granting Paladin Labs, Inc. exclusive marketing and distribution rights for MUSE in Canada. International product revenues from the sales of MUSE to these distributors is included in the financial statements and notes thereto appearing elsewhere in this Form 10-K. International operations are subject to certain additional risks inherent in conducting business outside the United States, including changes in overseas economic and political conditions, terrorism, currency exchange rates, foreign tax laws and tariffs and other governmental action.

Available Information

Our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to reports filed pursuant to Section 13(a) and 15(d) of the Securities Exchange Act of 1934, as amended, are available on our website at *www.vivus.com*, when such reports are available on the Securities and Exchange Commission website.

Additionally, copies of our annual report will be made available, free of charge, upon written request.

ITEM 1A. *Risk Factors*

Set forth below and elsewhere in this Annual Report on Form 10-K and in other documents we file with the Securities and Exchange Commission (SEC) are risks and uncertainties that could cause actual results to differ materially from the results contemplated by the forward-looking statements contained in this Annual Report on Form 10-K. These are not the only risks and uncertainties facing VIVUS. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations.

Risks Relating to our Product Development Efforts

We face significant risks in our product development efforts.

The process of developing new drugs and/or therapeutic products is inherently complex, time-consuming, expensive and uncertain. We must make long-term investments and commit significant resources before knowing whether our development programs will result in products that will receive regulatory approval and achieve market acceptance. Product candidates that may appear to be promising at early stages of development may not reach the market for a number of reasons. Product candidates may be found ineffective or may cause harmful side effects during clinical trials, may take longer to progress through clinical trials than had been anticipated, may fail to receive necessary regulatory approvals, may prove impracticable to manufacture in commercial quantities at reasonable cost and with acceptable quality, or may fail to achieve market acceptance.

If the results of future clinical testing indicate that our proposed products are not safe or effective for human use, our business will suffer.

All of the drug candidates that we are currently developing require extensive pre-clinical and clinical testing before we can submit any application for regulatory approval. Before obtaining regulatory approvals for the commercial sale of any of our proposed drug products, we must demonstrate through pre-clinical testing and clinical trials that our product candidates are safe and effective in humans. Conducting clinical trials is a lengthy, expensive and uncertain process. Completion of clinical trials may take several years or more. Our ability to complete clinical trials may be delayed by many factors, including:

inability to manufacture sufficient quantities of compounds for use in clinical trials;

failure to receive approval by the United States Food and Drug Administration, or FDA, of our clinical trial protocols;

changes in clinical trial protocols imposed by the FDA;

the effectiveness of our product candidates;

slower than expected rate of and higher than expected cost of patient recruitment;

inability to adequately follow patients after treatment;

unforeseen safety issues; or

government or regulatory delays.

To date, the clinical results we have obtained do not necessarily predict that the results of further testing, including later stage controlled human clinical testing, will be successful. If our trials are not successful or are perceived as not successful by the FDA or physicians, our business, financial condition and results of operations will be materially harmed.

We are exposed to risks related to collaborative arrangements or strategic alliances.

We are, and in the future expect to be, dependent upon collaborative arrangements or strategic alliances to complete the development and commercialization of some of our drug candidates particularly after the Phase 2 stage of clinical testing. These arrangements may place the development of our drug candidates outside of our control, may require us to relinquish important rights, or may otherwise be on terms unfavorable to us.

We may be unable to locate and enter into favorable agreements with third parties, which could delay or impair our ability to develop and commercialize our drug candidates and could increase our costs of development and commercialization. Dependence on collaborative arrangements or strategic alliances will subject us to a number of risks, including the risk that:

we may not be able to control the amount and timing of resources that our collaborators may devote to the drug candidates;

our collaborators may experience financial difficulties;

we may be required to relinquish important rights such as marketing and distribution rights;

business combinations or significant changes in a collaborator s business strategy may also adversely affect a collaborator s willingness or ability to complete its obligations under any arrangement;

a collaborator could independently move forward with a competing drug candidate developed either independently or in collaboration with others, including our competitors; and

collaborative arrangements are often terminated or allowed to expire, which would delay the development and may increase the cost of developing our drug candidates.

We face significant governmental regulation during our product development activities.

The research, testing, manufacturing, selling and marketing of drug candidates are subject to extensive regulations by the FDA and other regulatory agencies in the United States and other countries. We cannot predict with certainty if or when we might submit for regulatory review those product candidates currently under development. The FDA can suspend clinical studies at any time if the agency believes that the subjects participating in such studies are being exposed to unacceptable health risks.

Regulatory approval is never guaranteed, and the approval process typically takes several years and is extremely expensive. The FDA has substantial discretion in the drug approval process. Despite the time and expense involved, failure can occur at any stage, and we could encounter problems that cause us to abandon clinical trials or to repeat or perform additional pre-clinical trials and clinical trials. The number of pre-clinical studies and clinical trials that will be required for FDA approval varies depending on the drug candidate, the disease condition that the drug candidate is designed to address, and the regulations applicable to any particular drug candidate. The FDA could determine that additional studies are required before and after a product candidate will be approved.

For example, in December 2004, an FDA advisory panel recommended against approval of a testosterone patch being developed by another company to address female sexual dysfunction, specifically hypoactive sexual desire disorder, and indicated that more safety data would be required before it would be in a position to recommend approval. Subsequently, this company withdrew its New Drug Application, or NDA. We are also developing a transdermal testosterone product candidate, Testosterone MDTS, which is designed to address hypoactive sexual desire disorder. In light of the FDA panel s recommendation, we may be required to undertake additional or expanded clinical trials, which could be expensive. As a result, we could experience significant delays in our ability to submit our product candidate to the FDA for consideration, and we may be unsuccessful in obtaining FDA approval of our product candidate.

We are not permitted to market any of our product candidates in the United States until we receive approval from the FDA. As a consequence, any failure to obtain or delay in obtaining FDA approval for our drug candidates would delay or prevent our ability to generate revenue from our product candidates, which would adversely affect our financial results and our business.

Our applications for regulatory approval could be delayed or denied due to problems with studies conducted before we licensed some of our product candidates from third parties.

We currently license some of our product candidates from third parties. Our present development programs involving these product candidates rely in part upon previous development work conducted by third parties over which we had no control and before we licensed the product candidates. In order to receive regulatory approval of a product candidate, we must present to the FDA for its review all relevant data and information obtained during research and development, including research conducted prior to our license of the product candidate. Although we are not currently aware of any such problems, any problems that emerge with research and testing conducted prior to our licensing a product candidate may affect future results or our ability to document prior research and to conduct clinical trials, which could delay, limit or prevent regulatory approval for our product candidates.

Following regulatory approval of any drug candidates, we would be subject to ongoing regulatory obligations and restrictions, which may result in significant expense and limit our ability to commercialize our potential drugs.

If one of our drug candidates is approved by the FDA or by another regulatory authority for a territory outside of the United States, we would be held to extensive regulatory requirements over product manufacturing, labeling, packaging, adverse event reporting, storage, advertising, promotion and record keeping. Regulatory approvals may also be subject to significant limitations on the indicated uses or marketing of the drug candidates. Potentially costly follow-up or post-marketing clinical studies may be required as a condition of approval to further substantiate safety or efficacy, or to investigate specific issues of interest to the regulatory authority. Previously unknown problems with the drug candidate, including adverse events of unanticipated severity or frequency, may result in restrictions on the marketing of the drug, and could lead to the withdrawal of the drug from the market.

In addition, the law or regulatory policies governing pharmaceuticals may change. New statutory requirements may be enacted or additional regulations may be enacted that could prevent or delay regulatory approval of our drug candidates. We cannot predict the likelihood, nature or extent of adverse government regulation that may arise from future legislation or administrative action, either in the United States or elsewhere. If we are not able to maintain regulatory compliance, we might not be permitted to market our drugs and our business could suffer.

We rely on third parties to conduct clinical trials for our product candidates in development and those third parties may not perform satisfactorily.

Like many companies our size, we do not have the ability to conduct clinical studies for our product candidates without the assistance of third parties who conduct the studies on our behalf. These third parties are usually clinical research organizations, or CROs, that have significant resources and experience in the conduct of clinical studies. The CROs typically perform patient recruitment, project management, data management, statistical analysis, and other reporting functions. We intend to use several different CROs for all of our clinical studies. If these third party CROs do not successfully carry out their contractual duties or meet expected timelines, we may not be able to obtain regulatory approvals for our proposed products on a timely basis, if at all, and we may not be able to successfully commercialize these proposed products. If these third party CROs do not perform satisfactorily, we may not be able to locate acceptable replacements or enter into favorable agreements with them, if at all.

We rely on third parties to manufacture sufficient quantities of compounds for use in our pre-clinical and clinical trials and an interruption to this service may harm our business.

We do not have the ability to manufacture the materials we use in our pre-clinical and clinical trials. Rather, we rely on various third parties to manufacture these materials. There can be no assurance that we will be able to identify and qualify additional sources for clinical materials. If interruptions in this supply occur for any reason, including a decision by the third parties to discontinue manufacturing, labor disputes or a failure of the third parties to follow regulations, we may not be able to obtain regulatory approvals for our proposed products and may not be able to successfully commercialize these proposed products.

Risks Relating to our Operations

If we, or our suppliers, fail to comply with FDA and other government regulations relating to our manufacturing operations, we may be prevented from manufacturing our products or may be required to undertake significant expenditures to become compliant with regulations.

After regulatory approval for a drug candidate is obtained, the candidate is subject to continual regulatory review. Manufacturing, labeling and promotional activities are continually regulated by the FDA and equivalent foreign regulatory agencies. For example, our third-party manufacturers are required to maintain satisfactory compliance with current Good Manufacturing Practices, or cGMPs. If these manufacturers fail to comply with applicable regulatory requirements, our ability to manufacture, market and distribute our products may be adversely affected. In addition, the FDA could issue warning letters or could require the seizure or recall of products. The FDA could also impose civil penalties or require the closure of our manufacturing facility until cGMP compliance is achieved.

We obtain the necessary raw materials and components for the manufacture of MUSE as well as certain services, such as testing and sterilization, from third parties. We currently contract with suppliers and service providers, including foreign manufacturers. We and these suppliers and service providers are required to follow cGMP requirements and are subject to routine and unannounced inspections by the FDA and by state and foreign regulatory agencies for compliance with cGMP requirements and other applicable regulations. Upon inspection of these facilities, the FDA or foreign regulatory agencies may find the manufacturing process or facilities are not in compliance with cGMP requirements and other regulations.

We are required to obtain FDA approval for any change in suppliers or service providers. For example, MUSE is supplied to the market with the MUSE applicator, containing the MUSE dosage, enclosed within a sealed foil pouch. Our supplier that produces the

MUSE laminated foil has closed their business. The laminated foil is used to make the sealed foil pouch, described above, which is used to make the MUSE primary product container. Before the supplier closed their business, the supplier produced a bulk-quantity of foil that, at this time, is expected to be sufficient to support MUSE production through the end of 2006. There can be no assurance that as this bulk supply is used over the next year there will be a sufficient yield in the final quantity of foil with acceptable quality to support MUSE demand through 2006. Although the foil supplier produced this bulk unprinted foil, the label printing will be done periodically during 2006. As a consequence, if there are unacceptable quality issues with the bulk foil, they may not be discovered until sometime in 2006. If such foil quality issues do occur, we may be unable to meet MUSE demand during 2006.

We have identified a new potential vendor for the MUSE laminated foil. As this laminated foil is used to make the MUSE primary product container, there are significant qualifications and regulatory approvals that must be obtained prior to using the new vendor to produce foil to meet MUSE demand. These include, but are not limited to, vendor qualification, foil material qualification, MUSE product suitability studies, electron beam irradiation suitability, FDA approval, and European Medicines and Healthcare products Regulatory Agency approval. There can be no assurance that these qualifications and approvals will be successfully obtained, or that they will be obtained within the time needed to support MUSE demand before the supply of foil from our current vendor is exhausted.

Failure to receive adequate supplies of foil, failure to receive appropriate regulatory approvals for the change in materials and vendors, and any unforeseen quality or production issues due to the use of the new materials or vendors could have a material adverse effect on our business, financial condition and results of operations.

Failure to achieve satisfactory cGMP compliance as confirmed by routine and unannounced inspections could have a material adverse effect on our ability to continue to manufacture and distribute our products and, in the most serious case, result in the issuance of a regulatory warning letter or seizure or recall of products, injunction and/or civil penalties or closure of our manufacturing facility until cGMP compliance is achieved.

Our marketing activities for our products are subject to continued governmental regulation.

After product approval by the FDA, our labeling and marketing activities continue to be subject to FDA and other regulatory review. If products are marketed in contradiction with FDA mandates, the FDA may issue warning letters that require specific remedial measures to be taken, as well as an immediate cessation of the impermissible conduct. The FDA may also order that all future promotional materials receive prior agency review and approval before use. For example, the FDA issued a warning letter to us in May 2004 in which the FDA objected to a specific television commercial as well as information contained on our website promoting MUSE, our FDA approved product for the treatment of erectile dysfunction. The letter indicated that we had failed to disclose or had minimized certain risks associated with MUSE. Through discussions with the FDA, we agreed to produce and have released a television commercial that we believe addressed the FDA s concerns. We incurred costs in providing this corrective information, which would have otherwise been utilized by us in a different manner. In March 2005, we received a letter from the FDA indicating that the matter had been closed.

Results from a single center study reported in mid-2005 show a potential benefit from the therapeutic use of MUSE following radical prostatectomy. This use of MUSE is not included in the current label. We are sponsoring clinical trials to study the effects of MUSE therapy following radical prostatectomy. We believe physicians are beginning to prescribe MUSE for use following radical prostatectomy. Should the use of MUSE for this indication be altered, future sales of MUSE could be negatively affected.

We must continue to monitor the use of our approved drugs and may be required to complete post-approval studies mandated by the FDA.

Even if we receive regulatory approval of our products, such approval may involve limitations on the indicated uses or marketing claims we may make for our products. Further, later discovery of previously unknown problems could result in additional regulatory restrictions, including withdrawal of products. The FDA may also require us to commit to perform lengthy post-approval studies, for which we would have to expend significant additional resources, which could have an adverse effect on our operating results and financial condition. Failure to comply with the applicable regulatory requirements can result in, among other things, civil penalties, suspensions of regulatory approvals, product recalls, operating restrictions and criminal prosecution. The restriction, suspension or revocation of regulatory approvals or any other failure to comply with regulatory requirements could have a material adverse effect on our business, financial condition and results of operations.

We depend exclusively on third-party distributors outside of the United States and we have very limited control over their activities.

We entered into an agreement granting Meda AB exclusive marketing and distribution rights for MUSE in member states of the European Union, the Baltic States, the Czech Republic, Hungary, Iceland, Norway, Poland, Switzerland and Turkey. This agreement does not have minimum purchase commitments and we are entirely dependent on Meda s efforts to distribute and sell MUSE

effectively in all these markets. There can be no assurance that such efforts will be successful or that Meda will continue to support MUSE.

We entered into an agreement granting Paladin Labs, Inc. exclusive marketing and distribution rights for MUSE in Canada. This agreement does not have minimum purchase commitments and we are entirely dependent on Paladin Labs efforts to distribute and sell our product effectively in Canada. There can be no assurance that such efforts will be successful or that Paladin Labs will continue to support the product.

Sales of our current and any future products are subject to continued governmental regulation, our ability to accurately forecast demand and our ability to produce sufficient quantities to meet demand.

Sales of our products both inside and outside the United States will be subject to regulatory requirements governing marketing approval. These requirements vary widely from country to country and could delay the introduction of our proposed products in those countries. After the FDA and international regulatory authorities approve a product, we must manufacture sufficient volumes to meet market demand. This is a process that requires accurate forecasting of market demand. There is no guarantee that there will be market demand for any future products or that we will be able to successfully manufacture or adequately support sales of any future products.

We have limited sales and marketing capabilities in the United States.

We support MUSE sales in the United States through a small direct sales force targeting major accounts. Telephone marketers also focus on urologists who prescribe MUSE. Physician and patient information/help telephone lines are available to answer additional questions that may arise after reading the inserts or after actual use of the product. The sales force actively participates in national urologic and sexual dysfunction forums and conferences, such as the American Urological Association annual and regional meetings and the International Society for Impotence Research. There can be no assurance that our sales programs will effectively maintain or potentially increase current sales levels. There can be no assurance that demand for MUSE will continue or that we will be able to adequately support sales of MUSE in the United States in the future.

We have little or no control over our wholesalers buying patterns, which may impact future revenues, returns and excess inventory.

For domestic sales we sell our product primarily to major wholesalers located in the United States. Consistent with the pharmaceutical industry, most of our revenues are derived from the three major wholesalers. We rely solely on our wholesaler customers to effect the distribution allocation of our product. There can be no assurance that these customers will adequately manage their local and regional inventories to avoid outages, build-ups or result in excessive returns for expiration.

We do not control or significantly influence the purchasing patterns of wholesale customers. These are highly sophisticated customers that purchase our product in a manner consistent with their industry practices and perceived business interests. Our sales are subject to the purchasing requirements of our major customers, which presumably are based upon projected volume levels. Purchases by any customer, during any period may be above or below the actual prescription volumes of our product during the same period, resulting in increases or decreases in inventory existing in the distribution channel.

The markets in which we operate are highly competitive and we may be unable to compete successfully against new entrants or established companies.

Competition in the pharmaceutical and medical products industries is intense and is characterized by extensive research efforts and rapid technological progress. Several pharmaceutical companies are also actively engaged in the development of therapies for the treatment of erectile dysfunction and female sexual dysfunction. These companies have substantially greater research and development capabilities as well as substantially greater marketing, financial and human resources than we do. In addition, many of these companies have significantly greater experience than us in undertaking pre-clinical testing, human clinical trials and other regulatory approval procedures. Our competitors may develop technologies and products that are more effective than those we are currently marketing or developing. Such developments could render our products less competitive or possibly obsolete. We are also competing with respect to marketing capabilities and manufacturing efficiency, areas in which we have limited experience.

The most significant competitive therapy for MUSE is an oral medication marketed by Pfizer, Inc. under the name Viagra®, which received regulatory approvals in the United States in March 1998 and in the European Union in September 1998. The commercial launch of Viagra in the United States in April 1998 significantly decreased demand for MUSE. In February 2003, a new oral medication under the name Cialis® was launched in Europe by Lilly ICOS LLC and in Australia and New Zealand by Eli Lilly and Company alone. Lilly ICOS LLC launched Cialis in the United States in November 2003. Bayer AG and GlaxoSmithKline plc launched Levitra® in the European Union and the United States in March and September 2003, respectively.

If our raw material suppliers fail to supply us with alprostadil, for which availability is limited, we may experience delays in our product development and commercialization.

We are required to receive regulatory approval for suppliers. We obtained our current supply of alprostadil from two approved sources, NeraPharm, s.r.o., in the Czech Republic and Chinoin Pharmaceutical and Chemical Works Co., Ltd., in Hungary. We have manufacturing agreements with Chinoin and NeraPharm to produce additional quantities of alprostadil for us. We are currently in the process of investigating additional sources for our future alprostadil supplies. However, there can be no assurance that we will be able to identify and qualify additional suppliers of alprostadil in a timely manner, or at all.

Furthermore, our current supply of alprostadil is subject to periodic re-testing to ensure it continues to meet specifications. There can be no guarantees that our existing inventory of alprostadil will pass these re-testing procedures and continue to be usable material. There is a long lead-time for manufacturing alprostadil. A shortage in supply of alprostadil to be used in the manufacture of MUSE would have a material adverse effect on our business, financial condition and results of operations.

We outsource several key parts of our operations, and any interruption in the services provided by third parties could harm our business.

Under our outsourcing agreement with Cardinal Health, Inc. related to MUSE, Cardinal Health warehouses our finished goods for United States distribution; takes customer orders; picks, packs and ships our products; invoices customers; and collects related receivables. As a result of this distribution agreement, we are heavily dependent on Cardinal Health s efforts to fulfill orders and warehouse our products effectively in the United States. There can be no assurance that such efforts will continue to be successful.

Under our testing agreement, Gibraltar Laboratories performs sterility testing on finished product manufactured by us to ensure that it complies with product specifications. Gibraltar Laboratories also performs microbial testing on water and compressed gases used in the manufacturing process and microbial testing on environmental samples to ensure that the manufacturing environment meets appropriate cGMP regulations and cleanliness standards. As a result of this testing agreement, we are dependent on Gibraltar Laboratories to perform testing and issue reports on finished product and the manufacturing environment in a manner that meets cGMP regulations.

We have an agreement with WRB Communications to handle patient and healthcare professional hotlines to answer questions and inquiries about MUSE. Calls to these hotlines may include complaints about our products due to efficacy or quality, as well as the reporting of adverse events. As a result of this agreement, we are dependent on WRB Communications to effectively handle these calls and inquiries. There can be no assurance that such efforts will be successful.

We entered into a distribution agreement with Integrated Commercialization Services, or ICS, a subsidiary of AmerisourceBergen Corporation. ICS provides direct-to-physician distribution of product samples in support of United States marketing and sales efforts. As a result of this distribution agreement, we are dependent on ICS s efforts to distribute product samples effectively.

We rely on two companies, E-Beam Services, Inc. (E-Beam) and Beam One, LLC (Beam One), for the sterilization of MUSE. However, for some international markets, the MUSE Product License includes approval to use only one of the above listed vendors. If interruptions in these

services occur for any reason, including a decision by E-Beam or Beam One to discontinue manufacturing or services, political unrest, labor disputes or a failure of E-Beam or Beam One to follow regulations, the commercial marketing of MUSE and the development of other potential products could be prevented or delayed. An extended interruption in sterilization services would have a material adverse effect on our business, financial condition and results of operations.

We currently depend on a single source for the supply of plastic applicator components for MUSE, and an interruption to this supply source could harm our business.

We rely on a single injection molding company, Medegen Medical Products, LLC, for our supply of plastic applicator components. In turn, Medegen obtains its supply of resin, a key ingredient of the applicator, from a single source, Huntsman Corporation. There can be no assurance that we will be able to identify and qualify additional sources of plastic components or that Medegen will be able to identify and qualify additional sources of resin. We are required to receive FDA approval for new suppliers. Until we secure and qualify additional sources of plastic components, we are entirely dependent upon Medegen. If interruptions in this supply occur for any reason, including a decision by Medegen to discontinue manufacturing, labor disputes or a failure of Medegen to follow regulations, the manufacture and marketing of MUSE and other potential products could be delayed or prevented. An extended interruption in the supply of plastic components could have a material adverse effect on our business, financial condition or results of operations.

All of our manufacturing operations are currently conducted at a single location, and a prolonged interruption to our manufacturing operations could harm our business.

We purchased two buildings with a total combined 90,000 square feet in Lakewood, New Jersey, which we previously leased, on December 22, 2005. This facility is used for our manufacturing operation, which includes formulation, filling, packaging, analytical laboratories, storage, distribution and administrative offices. The FDA and the Medicines and Healthcare products Regulatory Agency, the regulatory authority in the United Kingdom, authorized us to begin commercial production and shipment of MUSE from this facility in June and March 1998, respectively. MUSE is manufactured in this facility and we have no immediate plans to construct another manufacturing site. Since MUSE is produced with custom-made equipment under specific manufacturing conditions, the inability of our manufacturing facility to produce MUSE for whatever reason could have a material adverse effect on our business, financial condition and results of operations.

We are dependent upon a single approved therapeutic approach to treat erectile dysfunction.

MUSE relies on a single approved therapeutic approach to treat erectile dysfunction, a transurethral system. The existence of side effects or dissatisfaction with this product may impact a patient s decision to use or continue to use, or a physician s decision to recommend, this therapeutic approach as a therapy for the treatment of erectile dysfunction, thereby affecting the commercial viability of MUSE. In addition, technological changes or medical advancements could further diminish or eliminate the commercial viability of our product, the results of which could have a material effect on our business operations and results.

If we fail to retain our key personnel and hire, train and retain qualified employees, we may not be able to compete effectively, which could result in reduced revenues.

Our success is highly dependent upon the skills of a limited number of key management personnel. To reach our business objectives, we will need to retain and hire qualified personnel in the areas of manufacturing, sales and marketing, research and development, regulatory affairs, clinical trial management and pre-clinical testing. There can be no assurance that we will be able to hire or retain such personnel, as we must compete with other companies, academic institutions, government entities and other agencies. The loss of any of our key personnel or the failure to attract or retain necessary new employees could have an adverse effect on our research, product development and business operations.

We are subject to additional risks associated with our international operations.

MUSE is currently marketed internationally. Changes in overseas economic and political conditions, terrorism, currency exchange rates, foreign tax laws or tariffs or other trade regulations could have an adverse effect on our business, financial condition and results of operations. The international nature of our business is also expected to subject us and our representatives, agents and distributors to laws and regulations of the foreign jurisdictions in which we operate or where our products are sold. The regulation of drug therapies in a number of such jurisdictions, particularly in the European Union, continues to develop, and there can be no assurance that new laws or regulations will not have a material adverse effect on our business, financial condition and results of operations. In addition, the laws of certain foreign countries do not protect our intellectual property rights to the same extent as the laws of the United States.

Any adverse changes in reimbursement procedures by government and other third-party payors may limit our ability to market and sell our products or limit our product revenues and delay profitability.

In the United States and elsewhere, sales of pharmaceutical products are dependent, in part, on the availability of reimbursement to the consumer from third-party payors, such as government and private insurance plans. Third party payors are increasingly challenging the prices charged for medical products and services. While a large percentage of prescriptions in the United States for MUSE have been reimbursed by third party payors since our commercial launch in January 1997, there can be no assurance that our products will be considered cost effective and that reimbursement to the consumer will continue to be available or sufficient to allow us to sell our products on a competitive basis.

In addition, certain healthcare providers are moving towards a managed care system in which such providers contract to provide comprehensive healthcare services, including prescription drugs, for a fixed cost per person. We are unable to predict the reimbursement policies employed by third party healthcare payors. Furthermore, reimbursement for MUSE could be adversely affected by changes in reimbursement policies of governmental or private healthcare payors.

The healthcare industry is undergoing fundamental changes that are the result of political, economic and regulatory influences. The levels of revenue and profitability of pharmaceutical companies may be affected by the continuing efforts of governmental and third party payors to contain or reduce healthcare costs through various means. Reforms that have been and may be considered include mandated basic healthcare benefits, controls on healthcare spending through limitations on the increase in private health insurance premiums and the types of drugs eligible for reimbursement and Medicare and Medicaid spending, the creation of large insurance

purchasing groups and fundamental changes to the healthcare delivery system. Due to uncertainties regarding the outcome of healthcare reform initiatives and their enactment and implementation, we cannot predict which, if any, of the reform proposals will be adopted or the effect such adoption may have on us. There can be no assurance that future healthcare legislation or other changes in the administration or interpretation of government healthcare or third party reimbursement programs will not have a material adverse effect on us. Healthcare reform is also under consideration in some other countries.

The continuing efforts of government and third-party payors to contain or reduce the costs of health care through various means may reduce our potential revenues. These payors efforts could decrease the price that we receive for any products we may develop and sell in the future. In addition, third-party insurance coverage may not be available to patients for any products we develop. If government and third-party payors do not provide adequate coverage and reimbursement levels for our products, or if price controls are enacted, our product revenues will suffer.

Congress passed legislation that ended federal Medicaid and Medicare payments for erectile dysfunction drugs beginning January 1, 2006 and January 1, 2007, respectively. We are currently assessing the impact that this legislation will have on our business. However, historically the volume of MUSE sales to Medicaid and Medicare patients has not been a significant portion of our overall MUSE sales volume. We believe there is increasing political pressure to reduce or eliminate reimbursement by the U.S. government for MUSE. A reduction or elimination in the reimbursement by the U.S. government would have a material adverse impact on our revenues and business operations.

Defending against claims relating to improper handling, storage or disposal of hazardous materials could be time consuming and expensive.

Our research and development involves the controlled use of hazardous materials and our operations produce hazardous waste products. We cannot eliminate the risk of accidental contamination or discharge and any resultant injury from those materials. Various laws and regulations govern the use, manufacture, storage, handling and disposal of hazardous materials. We may be sued for any injury or contamination that results from our use or the use by third parties of these materials. Compliance with environmental laws and regulations may be expensive, and current or future environmental regulations may impair our research, development and production efforts.

Natural disasters or resource shortages could disrupt our operations and adversely affect results.

Our manufacturing operation is conducted in a single location in Lakewood, New Jersey. In the event of a natural disaster in that region, such as a storm, drought or flood, or localized extended outages of critical utilities or transportation systems, we do not have a formal business continuity or disaster plan, and could therefore experience a significant business interruption.

Furthermore, our clinical trials could be delayed or disrupted indefinitely upon the occurrence of a natural disaster. For example, our clinical trials in the New Orleans area were interrupted by Hurricane Katrina. Future natural disasters could further delay our clinical trials process, thus adversely affecting our business and financial results.

Risks Relating to our Intellectual Property

We may be sued for infringing the intellectual property rights of others.

There can be no assurance that our products do not or will not infringe on the patent or proprietary rights of others. Third parties may assert that we are employing their proprietary technology without authorization. For example, in October 2002, the United States Patent and Trademark Office (USPTO) issued to Pfizer a method of use U.S. Patent No. 6,469,012. Pfizer immediately initiated litigation against competitors who were selling PDE5 inhibitors, including ICOS, the maker of Cialis. In September 2003, the USPTO ordered the reexamination of the patent. In a related action, the European Patent Office revoked Pfizer s European patent. However, if the claims under the method of use patent are upheld by the USPTO, we may be prevented from commercializing avanafil, our PDE5 inhibitor.

In addition, third parties may obtain patents in the future and claim that use of our technologies infringes these patents. We could incur substantial costs and diversion of the time and attention of management and technical personnel in defending ourselves against any such claims. Furthermore, parties making claims against us may be able to obtain injunctive or other equitable relief that could effectively block our ability to further develop, commercialize and sell products, and such claims could result in the award of substantial damages against us. In the event of a successful claim of infringement against us, we may be required to pay damages and obtain one or more licenses from third parties. We may not be able to obtain these licenses at a reasonable cost, if at all. In that case, we could encounter delays in product introductions while we attempt to develop alternative methods or products or be required to cease commercializing affected products and our operating results would be harmed.

Our inability to adequately protect our proprietary technologies could harm our competitive position and have a material adverse effect on our business.

We hold various patents and patent applications in the United States and abroad targeting male and female sexual health. The success of our business depends, in part, on our ability to obtain patents and maintain adequate protection of our intellectual property for our proprietary technology and products in the United States and other countries. The laws of some foreign countries do not protect proprietary rights to the same extent as the laws of the United States, and many companies have encountered significant problems in protecting their proprietary rights in these foreign countries. These problems can be caused by, for example, a lack of rules and processes allowing for meaningful defense of intellectual property rights. If we do not adequately protect our intellectual property, competitors may be able to use our technologies and erode our competitive advantage, and our business and operating results could be harmed.

The patent positions of pharmaceutical companies, including our patent position, are often uncertain and involve complex legal and factual questions. We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our proprietary technologies are covered by valid and enforceable patents or are effectively maintained as trade secrets. We apply for patents covering our technologies and products, as we deem appropriate. However, we may not obtain patents on all inventions for which we seek patents, and any patents we obtain may be challenged and may be narrowed in scope or extinguished as a result of such challenges. We could incur substantial costs in proceedings before the USPTO, including interference proceedings. These proceedings could also result in adverse decisions as to the priority of our inventions. There can be no assurance that our patents will not be successfully challenged or designed around by others.

Our existing patents and any future patents we obtain may not be sufficiently broad to prevent others from practicing our technologies or from developing competing products. Others may independently develop similar or alternative technologies or design around our patented technologies or products. These companies would then be able to develop, manufacture and sell products that compete directly with our products. In that case, our revenues and operating results would decline.

We seek to protect our confidential information by entering into confidentiality agreements with employees, collaborators and consultants. Nevertheless, employees, collaborators or consultants may still disclose or misuse our confidential information, and we may not be able to meaningfully protect our trade secrets. In addition, others may independently develop substantially equivalent information or techniques or otherwise gain access to our trade secrets. Disclosure or misuse of our confidential information would harm our competitive position and could cause our revenues and operating results to decline.

We may be subject to claims that we or our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

As is commonplace in the pharmaceutical industry, we employ individuals who were previously employed at other pharmaceutical companies, including our competitors or potential competitors. Although we have no knowledge of any pending claims, we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

Risks Relating to our Financial Position and Need for Financing

We require additional capital for our future operating plans, and we may not be able to secure the requisite additional funding on acceptable terms, or at all.

Our capital resources are expected to continue to decline over the next several quarters as the result of spending on research and development projects, including clinical trials. On March 15, 2005, we sold 6,250,000 shares of our common stock at a price of $3.40 per share, providing us with net proceeds of $19.6 million. On December 22, 2005, we purchased from our landlord our principal manufacturing facility, which was previously leased, for $7.1 million. The purchase price was funded in part by $3.3 million of restricted cash, which was being held by the landlord as cash collateral for renovations to the facility upon the termination of the lease and the remainder with cash. On January 4, 2006, we obtained a $5.4 million loan from Crown Bank, N.A. (Crown), secured by the land and buildings, among other assets, located at our principal manufacturing facility and a $700,000 Certificate of Deposit held by Crown. The loan is payable over a 10-year term and the interest rate will be fixed at 8.25%, which is the prime rate plus 1% at the time of funding and then will be adjusted annually to a fixed rate for the year equal to the prime rate plus 1% with a floor of 7.5%.

We expect that our existing capital resources combined with future cash flows will be sufficient to support our operating activities into 2007. However, we anticipate that we will be required to obtain additional financing to fund the development of our research and development pipeline in future periods as well as to support the possible launch of any future products. Our future capital requirements will depend upon numerous factors, including:

the progress and costs of our research and development programs;

the scope, timing and results of pre-clinical testing and clinical trials;

patient recruitment and enrollment in current and future clinical trials;

the costs involved in seeking regulatory approvals for our product candidates;

the costs involved in filing and pursuing patent applications and enforcing patent claims;

the establishment of collaborations and strategic alliances;

the cost of manufacturing and commercialization activities and arrangements;

the results of operations;

demand for MUSE;

the cost, timing and outcome of regulatory reviews;

the rate of technological advances;

ongoing determinations of the potential commercial success of our products under development;

the level of resources devoted to sales and marketing capabilities; and

the activities of competitors.

To obtain additional capital when needed, we will evaluate alternative financing sources, including, but not limited to, the issuance of equity or debt securities, corporate alliances, joint ventures and licensing agreements. However, there can be no assurance that funding will be available on favorable terms, if at all. We cannot assure you that we will successfully develop our products under development or that our products, if successfully developed, will generate revenues sufficient to enable us to earn a profit. If we are unable to obtain additional capital, management may be required to explore alternatives to reduce cash used by operating activities, including the termination of research and development efforts that may appear to be promising to us, the sale of certain assets and the reduction in overall operating activities.

We have an accumulated deficit of $147.0 million as of December 31, 2005 and expect to continue to incur substantial operating losses for the foreseeable future.

We have generated a cumulative net loss of $147.0 million for the period from our inception through December 31, 2005, and we anticipate losses for the next several years due to increased investment in our research and development programs and limited revenues. There can be no assurance that we will be able to achieve profitability or that we will be successful in the future.

If we become subject to product liability claims, we may be required to pay damages that exceed our insurance coverage.

The commercial sale of MUSE and our clinical trials expose us to a significant risk of product liability claims. In addition, pharmaceutical products are subject to heightened risk for product liability claims due to inherent side effects. We identify potential side effects in the patient package insert and the physician package insert, both of which are distributed with MUSE. While we believe that we are reasonably insured against these risks, we may not be able to obtain insurance in amounts or scope sufficient to provide us with adequate coverage against all potential liabilities. A product liability claim in excess of, or excluded from, our insurance coverage would have to be paid out of cash reserves and could have a material adverse effect upon our business, financial condition and results of operations. Product liability insurance is expensive, difficult to maintain, and current or increased coverage may not be available on acceptable terms, if at all.

Risks Relating to an Investment in our Common Stock

Our stock price has been and may continue to be volatile.

The market price of our common stock has been volatile and is likely to continue to be so. The market price of our common stock may fluctuate due to factors including, but not limited to:

announcements of technological innovations or new products by us or our competitors;

announcements by licensors of our technology;

our ability to increase demand for our products in the United States and internationally;

our ability to successfully sell our products in the United States and internationally;

actual or anticipated fluctuations in our financial results;

our ability to obtain needed financing;

economic conditions in the United States and abroad;

comments by or changes in assessments of us or financial estimates by security analysts;

adverse regulatory actions or decisions;

any loss of key management;

the results of our clinical trials or those of our competitors;

developments or disputes concerning patents or other proprietary rights;

product or patent litigation; and

public concern as to the safety of products developed by us.

These factors and fluctuations, as well as political and market conditions, may materially adversely affect the market price of our common stock. Securities class action litigation is often brought against a company following periods of volatility in the market price of its securities. We may be the target of similar litigation. Securities litigation, whether with or without merit, could result in substantial costs and divert management s attention and resources, which could harm our business and financial condition, as well as the market price of our common stock.

Additionally, volatility or a lack of positive performance in our stock price may adversely affect our ability to retain key employees, all of whom have been granted stock options.

Volatility in the stock prices of other companies may contribute to volatility in our stock price.

The stock market in general, and the Nasdaq National Market and the market for life sciences companies in particular, have experienced significant price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies. Further, there has been particular volatility in the market prices of securities of early stage and development stage life sciences companies. These broad market and industry factors may seriously harm the market price of our common stock, regardless of our operating performance.

Our share ownership is concentrated, and our officers, directors and principal stockholders can exert significant control over matters requiring stockholder approval.

Due to their combined stock holdings, our officers, directors and principal stockholders (stockholders holding greater than 5% of our common stock) acting collectively may have the ability to exercise significant influence over matters requiring stockholder approval including the election of directors and approval of significant corporate transactions. In addition, this concentration of

ownership may delay or prevent a change in control of VIVUS and may make some transactions more difficult or impossible to complete without the support of these stockholders.

Our operating results may fluctuate from quarter to quarter and this fluctuation may cause our stock price to decline.

Our quarterly operating results have fluctuated in the past and are likely to fluctuate in the future. Factors contributing to these fluctuations include, among other items, the timing and enrollment rates of clinical trials for our drug candidates, the timing of significant purchases of MUSE by distributors, and our need for clinical supplies. Thus, quarter-to-quarter comparisons of our operating results are not indicative of what we might expect in the future. As a result, in some future quarters our operating results may not meet the expectations of securities analysts and investors, which could result in a decline in the price of our stock.

There may not be an active, liquid trading market for our common stock.

There is no guarantee that an active trading market for our common stock will be maintained on the Nasdaq National Market. Investors may not be able to sell their shares quickly or at the latest market price if trading in our stock is not active.

Our charter documents and Delaware law could make an acquisition of our company difficult, even if an acquisition may benefit our stockholders.

Some provisions of our Amended and Restated Certificate of Incorporation and Bylaws could delay or prevent a change in control of our company. Some of these provisions:

authorize the issuance of preferred stock by the Board of Directors without prior stockholder approval, commonly referred to as blank check preferred stock, with rights senior to those of common stock;

prohibit stockholder actions by written consent;

specify procedures for director nominations by stockholders and submission of other proposals for consideration at stockholder meetings; and

eliminate cumulative voting in the election of directors.

In addition, we are governed by the provisions of Section 203 of Delaware General Corporate Law. These provisions may prohibit large stockholders, in particular those owning 15% or more of our outstanding voting stock, from merging or combining with us. These and other provisions in our charter documents could reduce the price that investors might be willing to pay for shares of our common stock in the future and result in the market price being lower than it would be without these provisions.

Changes in accounting standards regarding stock option plans could limit the desirability of granting stock options, which could harm our ability to attract and retain employees, and could also reduce our profitability.

In December 2004, the FASB issued revised statement No. 123 (FAS 123R), *Share-Based Payment*, which requires companies to expense the estimated fair value of employee stock options and similar awards. In April 2005, the SEC announced the adoption of a new rule that amended the compliance dates for FAS 123R. The accounting provisions of FAS 123R will now be effective for the first quarter of fiscal 2006. We will adopt the provisions of FAS 123R using a modified prospective application. Under modified prospective application, FAS 123R, which provides certain changes to the method for valuing stock-based compensation among other changes, will apply to new awards and to awards that are outstanding on the effective date and are subsequently modified or cancelled. Further compensation expense for outstanding awards for which the requisite service had not been rendered as of the effective date will be recognized over the remaining service period using the compensation cost calculated for pro forma disclosure purposes under FAS 123. The impact of the adoption of FAS 123R cannot be predicted at this time because it will be depend on levels of share-based payments granted in the future. However, valuation of employee stock options under FAS 123R is similar to FAS 123, with minor exceptions. The impact on the results of operations and earnings per share had VIVUS adopted FAS 123, is described in the Stock Option Plans section of Note 1 to our Consolidated Financial Statements. Accordingly, the adoption of FAS 123R s fair value method will have a material impact on our results of operations, although it will have no impact on our overall financial position. FAS 123R also requires the benefits of tax deductions in excess of recognized compensation cost to be reported as a financing cash flow, rather than as an operating cash flow as required under current literature. This requirement will reduce net operating cash flows and increase net financing cash flows in periods after adoption. Due to timing of the release of FAS 123R, VIVUS has not yet completed the analysis of the ultimate impact that this new pronouncement will have on our results of operations. We are in the process of determining how the new method of valuing stock-based compensation as prescribed in FAS 123R will be applied to valuing stock-based awards granted after the effective date and the impact the recognition of compensation expense related to such awards will have on our consolidated financial statements. When we are required to expense stock option grants, it will reduce the attractiveness of

granting stock options because of the additional expense associated with these grants. However, stock options are an important employee recruitment and retention tool, and we may not be able to attract and retain key personnel if we reduce the scope of our employee stock option program.

In March 2005, the SEC staff issued guidance on FAS 123R. Staff Accounting Bulletin No. 107 (SAB 107) was issued to assist preparers by simplifying some of the implementation challenges of FAS 123R while enhancing the information that investors receive. SAB 107 creates a framework that is premised on two overarching themes: (a) considerable judgment will be required by preparers to successfully implement FAS 123R, specifically when valuing employee stock options; and (b) reasonable individuals, acting in good faith, may conclude differently on the fair value of employee stock options. Key topics covered by SAB 107 include: (a) valuation models SAB 107 reinforces the flexibility allowed by FAS 123R to choose an option-pricing model that meets the standard s fair value measurement objective; (b) expected volatility the SAB provides guidance on when it would be appropriate to rely exclusively on either historical or implied volatility in estimating expected volatility; and (c) expected term the new guidance includes examples and some simplified approaches to determining the expected term under certain circumstances. We will apply the principles of SAB 107 in conjunction with its adoption of FAS 123R.

Compliance with changing regulation of corporate governance and public disclosure may result in additional expenses.

Changing laws, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act of 2002, new SEC regulations and Nasdaq National Market rules, are creating uncertainty for companies such as ours. These new or changed laws, regulations and standards are subject to varying interpretations in many cases due to their lack of specificity, and as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies, which could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We are committed to maintaining high standards of corporate governance and public disclosure. As a result, our efforts to comply with evolving laws, regulations and standards have resulted in, and are likely to continue to result in, increased general and administrative expenses and management time related to compliance activities. In particular, our efforts to comply with Section 404 of the Sarbanes-Oxley Act of 2002 and the related regulations regarding our required assessment of our internal controls over financial reporting and our external auditors audit of that assessment has required the commitment of significant financial and managerial resources. We expect these efforts to require the continued commitment of significant resources. If we fail to comply with new or changed laws, regulations and standards, our reputation may be harmed and we might be subject to sanctions or investigation by regulatory authorities, such as the Securities and Exchange Commission. Any such action could adversely affect our financial results and the market price of our common stock.

Item 1B. ***Unresolved Staff Comments***

None.

Item 2. ***Properties***

On December 22, 2005,VIVUS purchased two buildings with a combined 90,000 square feet of previously leased space in Lakewood New Jersey for our manufacturing operation, which includes formulation, filling, packaging, analytical laboratories, storage, distribution and administrative offices. The United States Food and Drug Administration and the Medicines and Healthcare products Regulatory Agency, formerly the Medicines Control Agency, the regulatory authority in the United Kingdom, authorized us to begin commercial production and shipment of MUSE from this facility in June and March 1998, respectively. We have met all market demands for the supply of MUSE utilizing this manufacturing facility and currently have the capacity to manufacture additional quantities of MUSE if required.

VIVUS leases 14,237 square feet of space in Mountain View, California, which serves as the principal site for administration, clinical trial management, regulatory affairs and our research and development activities.

In general, our existing facilities owned or leased are in good condition and adequate for all present and near term uses.

Item 3. ***Legal Proceedings***

In the normal course of business, VIVUS receives and makes inquiries regarding patent infringement and other legal matters. We have received notice from a former employee seeking payment due to their termination in 2005. We believe the employee has no claim to additional compensation and we will seek to conclude this matter without a material impact on our financial position. We believe that we have meritorious claims and defenses and intend to pursue any such matters vigorously. We are not aware of any asserted or unasserted claims against us where the resolution would have an adverse material impact on our operations or financial position.

Item 4. ***Submission of Matters to a Vote of Security Holders***

None.

PART II

Item 5. ***Market for Registrant s Common Equity and Related Stockholder Matters***

VIVUS s common stock trades publicly on the Nasdaq National Market System under the symbol VVUS. The following table sets forth for the periods indicated the quarterly high and low closing sales prices of the our common stock as reported on the Nasdaq National Market.

	Three Months Ended			
	March 31	June 30	September 30	December 31
2005				
High	$ 4.54	$ 3.95	$ 4.57	$ 3.54
Low	2.81	2.32	3.44	2.87
2004				
High	$ 7.20	$ 6.50	$ 5.10	$ 6.18
Low	4.13	3.61	3.61	4.27

Stockholders

As of February 24, 2006, there were 44,641,591 shares of outstanding common stock that were held by 4,331 shareholders of record and no outstanding shares of preferred stock. On February 24, 2006, the last reported sales price of our common stock on the NASDAQ National Market was $3.26 per share.

Dividends

We have not paid any dividends since our inception and we do not intend to declare or pay any dividends on our common stock in the foreseeable future. Declaration or payment of future dividends, if any, will be at the discretion of our Board of Directors after taking into account various factors, including VIVUS s financial condition, operating results and current and anticipated cash needs.

Stock Options

Our stock option plans are part of a broad-based, long-term retention program that is intended to attract and retain talented employees and directors and align stockholder and employee interests.

Pursuant to our 2001 Stock Option Plan, or the 2001 Plan, we may grant incentive or non-statutory stock options or stock purchase rights, or SPRs. The 2001 Plan allows us to grant incentive stock options to employees at not less than 100% of the fair market value of the stock (110%

of fair market value for individuals who control more than 10% of our stock) at the date of grant, as determined by the Board of Directors. The 2001 Plan allows us to grant non-statutory stock options to employees, directors and consultants at a price to be determined by the Board of Directors. The term of the option is determined by the Board of Directors on the date of grant but shall not be longer than ten years. The 2001 Plan allows us to grant SPRs to employees and consultants. Sales of stock under SPRs are made pursuant to restricted stock purchase agreements containing provisions established by the Board of Directors. We have a right, but not the obligation, to repurchase the shares at the original sale price, which expires at a rate to be determined by the Board of Directors. As of December 31, 2005, no SPRs have been granted under the 2001 Plan.

Additional information regarding our stock option plans and plan activity for fiscal 2005, 2004, and 2003 is provided in our consolidated financial statements. See Notes to Consolidated Financial Statements, Note 8 Stock Option and Purchase Plans .

Equity Compensation Plans Approved by Stockholders

Information about our equity compensation plans at December 31, 2005 that were approved by our stockholders was as follows:

Plan Category	Number of Shares to be issued Upon Exercise of Outstanding Options	Weighted Average Exercise Price of Outstanding Options	Number of Shares Remaining Available for Future Issuance
Equity compensation plans approved by stockholders (a)	4,404,664	$ 4.31	1,710,254
Equity compensation plans not approved by stockholders (b)		$	
Total	4,404,664	$ 4.31	1,710,254

(a) Consists of three plans: our 1991 Stock Option Plan, our 1994 Stock Option Plan and our 2001 Stock Option Plan.

(b) We do not have any plans that have not been approved by our stockholders.

Item 6. ***Selected Financial Data***

The following selected financial data have been derived from our audited financial statements. The information set forth below is not necessarily indicative of the results of future operations and should be read in conjunction with Management s Discussion and Analysis of Financial Condition and Results of Operations and the financial statements and notes thereto included elsewhere in this Annual Report on Form 10-K. The selected data is not intended to replace the financial statements.

Selected Financial Data
(In thousands, except per share)

Selected Annual Financial Data

	Year Ended December 31				
	2005	**2004**	**2003**	**2002**	**2001**
Income Statement Data:					
Product revenue United States, net	$ 11,697	$ 16,419	$ 18,953	$ 20,962	$ 19,560
Product revenue International	2,794	3,030	3,302	1,237	4,041
Other revenue	163	152	5,183	150	
Total revenue	14,654	19,601	27,438	22,349	23,601
Operating expenses:					
Cost of goods sold	11,018	11,283	10,993	11,207	12,933
Research and development	17,005	18,676	7,724	13,281	12,324
Selling, general and administrative	11,916	11,730	9,839	10,556	9,314
Total operating expenses	39,939	41,689	28,556	35,044	34,571
Loss from operations	(25,285)	(22,088)	(1,118)	(12,695)	(10,970)
Interest and other income, net	826	511	773	1,211	2,171
Loss before taxes	$ (24,459)	$ (21,577)	$ (345)	$ (11,484)	$ (8,799)
Net loss	$ (24,484)	$ (21,583)	$ (26)	$ (10,566)	$ (7,070)
Net loss per basic and diluted share	$ (0.57)	$ (0.57)	$ (0.00)	$ (0.32)	$ (0.22)
Shares used in per share computation	43,272	38,010	35,884	32,907	32,572
Balance Sheet Data (at year end):					
Working capital	$ 23,569	$ 25,466	$ 30,099	$ 18,974	$ 14,898
Total assets	$ 49,282	$ 54,389	$ 66,732	$ 49,681	$ 58,574
Long-term debt	$ 5,164	$ 3,239	$	$	$
Accumulated deficit	$ (147,027)	$ (122,543)	$ (100,960)	$ (100,934)	$ (90,368)
Stockholders equity	$ 26,601	$ 30,722	$ 51,235	$ 34,385	$ 43,975

Item 7. ***Management s Discussion and Analysis of Financial Conditions and Results of Operations***

Forward Looking Statement

This Management s Discussion and Analysis of Financial Conditions and Results of Operations and other parts of this Form 10-K contain forward-looking statements that involve risks and uncertainties. These statements typically may be identified by the use of forward-looking words or phrases such as believe, expect, intend, anticipate, should, planned, estimated, and potential, among others. All forward-looking statements included in this document are based on our current expectations, and we assume no obligation to update any such forward-looking statements. The Private Securities Litigation Reform Act of 1995 provides a safe harbor for such forward-looking statements. In order to comply with the terms of the safe harbor, we note that a variety of factors could cause actual results and experiences to differ materially from the anticipated results or other expectations expressed in such forward-looking statements. The risks and uncertainties that may affect the operations, performance, development, and results of our business include but are not limited to: (1) our history of losses and variable quarterly results; (2) substantial competition; (3) risks related to the clinical trial development of products not yet approved; (4) our reliance on sole source suppliers; (5) our limited sales and marketing efforts and our reliance on third parties; (6) failure to continue to develop innovative products; (7) risks related to noncompliance with United States Food and Drug Administration regulations; (8) risks related to the failure to protect our intellectual property and litigation in which we may become involved; and (9) other factors that are described from time to time in our periodic filings with the Securities and Exchange Commission, including those set forth in this filing as Item 1A. Risk Factors.

All percentage amounts and ratios were calculated using the underlying data in thousands. Operating results for the year ended December 31, 2005, are not necessarily indicative of the results that may be expected for future fiscal years. The following discussion and analysis should be read in conjunction with our historical financial statements and the notes to those financial statements that are included in Item 8. of Part II of this Form 10-K.

Overview

VIVUS, Inc. is a specialty pharmaceutical company focused on the research, development and commercialization of products to restore sexual function in women and men. Our product pipeline includes four clinical stage product candidates, each of which targets an estimated existing or potential market in excess of $1 billion annually. Evamist™, currently in Phase 3 development, is our product candidate to alleviate symptoms associated with menopause. Avanafil, which recently completed Phase 2 trials, is our phosphodiesterase type 5, or PDE5, inhibitor product candidate for the treatment of erectile dysfunction. ALISTA™, currently in Phase 2B trials, is our product candidate for the treatment of female sexual arousal disorder. Testosterone MDTS®, which recently completed a positive Phase 2 trial, is our product candidate to treat hypoactive sexual desire disorder.

In 1997, we launched MUSE® (alprostadil) in the United States and, together with our partners in 1998, internationally. We market MUSE as a prescription product for the treatment of erectile dysfunction. For international markets, we have entered into supply and distribution agreements with established pharmaceutical companies to market and distribute MUSE in various foreign countries. MUSE was the first minimally invasive therapy for erectile dysfunction available at a time when only more invasive therapies existed. Developing and bringing MUSE to the market provided us with experience in clinical and regulatory matters when the market for erectile dysfunction was in its infancy.

We have funded operations primarily through private and public offerings of our common stock and through product sales. We expect to generate future net losses due to increases in operating expenses as product candidates are advanced through the various stages of clinical development. As of December 31, 2005, we have incurred a cumulative deficit of $147.0 million and expect to incur operating losses in the near future.

Our Product Pipeline

We currently have four research and development programs targeting female and male sexual health:

Product	Indication	Status	Patent Expiry and Number
Evamist (Estradiol-MDTS)	Menopausal symptoms	Phase 3 ongoing	2017 (US 6,818,226)
ALISTA (topical alprostadil)	Female sexual arousal disorder (FSAD)	Phase 2B ongoing	2017 (US 5,877,216)
Testosterone MDTS	Hypoactive sexual desire disorder (HSDD)	Phase 2 completed	2017 (US 6,818,226)
Avanafil (PDE5 inhibitor)	Erectile dysfunction (ED)	Phase 2 completed	2020 (US 6,656,935)

Our Corporate Strategy

Our goal is to become a leader in the development and commercialization of innovative proprietary products for the treatment of female and male sexual health. We intend to achieve this by:

capitalizing on our clinical and regulatory expertise and experience in the field of sexual health to advance the development of product candidates in our pipeline;

establishing strategic relationships with marketing partners to maximize sales potential for our products that require significant commercial support; and

licensing complementary clinical stage products or technologies with competitive advantages from third parties for new and established markets.

Critical Accounting Policies and Estimates

The discussion and analysis of our financial condition and results of operations are based upon our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. On an on going basis, we evaluate our estimates, including those related to product returns, rebates and sales reserves, research and development expenses, doubtful accounts, income taxes, inventories and contingencies and litigation. We base our estimates on historical experience, information received from third parties and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

We believe the following critical accounting policies affect our more significant judgments and estimates used in the preparation of our consolidated financial statements:

Revenue Recognition: We recognize revenue when persuasive evidence of an arrangement exists, shipment has occurred, the sales price is fixed or determinable and collectibility is reasonably assured.

Product Returns: We have estimated reserves for product returns from wholesalers, hospitals and pharmacies. We estimate our reserves by utilizing historical information and data obtained from external sources. We record reserves for anticipated returns of expired or damaged product in the United States. We follow this method since

reasonably dependable estimates of product returns can be made based on historical experience. Revisions in returns estimates are charged to income in the period in which the facts that give rise to the revision become known. There is no right-of-return on product sold internationally subsequent to shipment; thus, no returns reserve is needed. We routinely assess our experience with product returns and adjust the reserves accordingly. For example, in the quarter ended June 30, 2005, we reduced our product returns reserve by $245,000 based on a decrease in historical returns experience. If actual product returns are greater than our estimates, additional reserves may be required.

Rebates and Sales Reserves: We have estimated reserves for government chargebacks for goods purchased by certain Federal government organizations including the Veterans Administration, Medicaid rebates to states for goods purchased by patients covered by Medicaid, other rebate programs and cash discounts for prompt payment. We estimate our reserves by utilizing historical information and data obtained from external sources. In estimating government chargeback reserves, we analyze actual chargeback amounts and apply historical chargeback rates to estimates of the quantity of units sold subject to chargebacks. In estimating Medicaid and other rebates, the historical rebate percentage is used to estimate future rebates. Effective January 1, 2006, MUSE will no longer qualify for Medicaid reimbursement, which we do not believe will have a significant impact on our business. For qualified customers, we grant payment terms of 2%, net 30 days. Allowances for cash discounts are estimated based upon the amount of trade accounts receivable subject to the cash discounts. We routinely assess our experience with cash discounts, Medicaid and other rebates and government chargebacks and adjust the reserves accordingly. If actual government chargebacks, Medicaid rebates, rebate and cash discounts are greater than our estimates, additional reserves may be required.

Research and Development Expenses: Research and development (R&D) expenses include license fees, related compensation, contractor fees, facilities costs, administrative expenses and clinical trials at other companies and research institutions under agreements which are generally cancelable, among other related R&D costs. All such costs are charged to R&D expense as incurred. We review and accrue clinical trials and other R&D expense based on work performed, which relies on estimates of total costs incurred based on patient enrollment, completion of studies and other events. We follow this method since reasonably dependable estimates of the costs applicable to various stages of a research

agreement or clinical trial can be made. Accrued clinical costs and other R&D expenses are subject to revisions as work progresses to completion. Revisions are charged to expense in the period in which the facts that give rise to the revision become known.

Allowance for Doubtful Accounts: We maintain allowances for doubtful accounts for estimated losses resulting from the inability of our customers to make required payments. If the financial condition of our customers were to deteriorate, resulting in an impairment of their ability to make payments, additional allowances could be required.

Income Taxes: We record a valuation allowance to reduce our deferred tax assets to the amount that is more likely than not to be realized. For all periods presented, we have recorded a full valuation allowance against our net deferred tax asset. While we have considered future taxable income and ongoing prudent and feasible tax planning strategies in assessing the need for the valuation allowance, in the event we were to determine that we would be able to realize our deferred tax assets in the future in excess of our net recorded amount, an adjustment to the deferred tax asset would increase income in the period such determination was made. We have also recorded income taxes payable for estimated current tax liabilities. We monitor these estimated liabilities and adjust them as conditions warrant.

Restructuring: In 1998, we experienced a significant restructuring and recorded restructuring related reserves for severance and employee costs, inventory obsolescence, raw material purchase commitments, property and related commitments, marketing commitments and other commitments. We monitor the adequacy of these liabilities and have made periodic adjustments as conditions have changed. On December 22, 2005, we purchased from our landlord our principal manufacturing facility, which was previously leased, for $7.1 million. The purchase price was funded in part by $3.3 million, which was being held by the landlord as cash collateral for renovations to the facility upon the termination of the lease and the remainder with cash. As a result, the $3.0 million restructuring reserve, which was related to the restoration liability on this facility, was eliminated and recorded as an adjustment against the purchase price of the building in December 2005.

Inventories: We record inventory reserves for estimated obsolescence or unmarketable inventory equal to the difference between the cost of inventory and the estimated market value based upon assumptions about future demand and market conditions. If actual market conditions are less favorable than those projected by management, additional inventory write-downs may be required. During the quarter ended September 30, 1998, we established significant reserves against our inventory to align with new estimates of expected future demand for MUSE. VIVUS had built up its inventory level prior to and after the launch of Viagra and had not anticipated the impact that Viagra would have on the demand for MUSE. As of December 31, 2005, the remaining inventory reserve balance is $3.8 million relating to raw materials and components. Some portion of the fully reserved inventory was used in production in 2003, 2004 and 2005. In the fourth quarter of 2004, we stopped using the fully reserved raw materials inventory in production and determined that we would not likely use this inventory in future production. In the first quarter of 2005, we determined that we likely would continue to use some portion of the fully reserved component parts in production. To the extent that this fully reserved inventory was used in production in 2003, 2004 and 2005, it was charged to cost of goods sold at a zero basis, which had a favorable impact on cost of goods sold.

Available-for-Sale Securities: Available-for-sale securities represent investments in debt securities that are stated at fair value. We restrict our cash investments to:

Direct obligations of the United States Treasury;

Federal Agency securities which carry the direct or implied guarantee of the United States government; and

Corporate securities, including commercial paper, rated A1/P1 or better.

The difference between amortized cost (cost adjusted for amortization of premiums and accretion of discounts which are recognized as adjustments to interest income) and fair value, representing unrealized holding gains or losses, are recorded in Accumulated Other Comprehensive Loss, a separate component of stockholders equity until realized.

Our policy is to record investments in debt securities as available-for-sale because the sale of such securities may be required prior to maturity. Any gains and losses on the sale of debt securities are determined on a specific identification basis and are included in interest and other income in the accompanying consolidated statements of operations. Available-for-sale securities with original maturities beyond one year from the balance sheet date are classified as non-current.

Contingencies and Litigation: We are periodically involved in disputes and litigation related to a variety of matters. When it is probable that we will experience a loss, and that loss is quantifiable, we record appropriate reserves.

Results of Operations

For the year ended December 31, 2005, we reported a net loss of $24.5 million, or $0.57 net loss per share, as compared to a net loss of $21.6 million, or $0.57 net loss per share, during the same period in 2004. The increased net loss in the year ended December 31, 2005, as compared to the year ended December 31, 2004, was primarily due to lower product revenues both in the United States and internationally offset by lower research and development costs in 2005 as compared to 2004.

For the year ended December 31, 2004, we reported a net loss of $21.6 million, or $0.57 net loss per share as compared to a net loss of $26,000, or no net loss per share, during the same period in 2003. The net loss was higher in 2004 as compared to 2003 primarily due to lower product sales of MUSE in the United States and internationally and higher research and development expenses including an aggregate $5.1 million in one time charges for licensing and milestone payments associated with three of our development programs, increased clinical trial and project activity for ALISTA, avanafil, Evamist and Testosterone MDTS, as well as the lack of the $5.0 million in other revenue resulting from the 2003 settlement of the Janssen Pharmaceutica arbitration claim.

We anticipate continued losses over the next several years because we expect MUSE sales to remain constant, and we plan to continue to invest in clinical development of our current research and development product candidates to bring those potential products to market.

Revenue

	(In thousands, except percentages) Years Ended December 31,			% Change Increase/(Decrease)	
	2005	2004	2003	05-04	04-03
United States product, net	$ 11,697	$ 16,419	$ 18,953	(29)%	(13)%
International product	2,794	3,030	3,302	(8)%	(8)%
Other revenue	163	152	5,183	7 %	(97)%
Total revenues	$ 14,654	$ 19,601	$ 27,438	(25)%	(29)%

Worldwide product revenues from the sales of MUSE were $14.5 million in 2005, a decrease of $5.0 million, or 25%, from the worldwide sales of MUSE in 2004. Product revenue in the United States for the year ended December 31, 2005 was $11.7 million, compared to $16.4 million for the year ended December 31, 2004. International product revenue was $2.8 million for the year ended December 31, 2005, compared to $3.0 million in the same period last year.

Domestic sales of MUSE were lower in the year ended December 31, 2005, as compared to the same period in 2004, mainly due to destocking of inventory at the wholesale level that occurred prior to the fourth quarter of 2005, a decline in the demand for MUSE, decreased purchases made by wholesalers in advance of the December 2005 price increase as compared to purchases in advance of the December 2004 price increase, and new U.S. government pricing which results in higher chargebacks. Similar to prior years, wholesalers made purchases in the fourth quarter that were greater than demand. Based on the fourth quarter 2005 demand for MUSE, we estimate purchases made by wholesalers in the fourth quarter of 2005 represent approximately four months of excess demand. As a result of the fourth quarter purchases by wholesalers, we expect our sales in the first half of 2006 will be reduced as experienced in the first half of 2004 and 2005. Demand for MUSE, as measured by independent third-party prescription data, has begun to stabilize but is down from the demand in 2004. International revenue also decreased as a result of lower shipments of MUSE to our international distribution partners in the year ended December 31, 2005 as compared to the prior year;

however, 63% of the shipments made in 2005 to our international partners took place in the fourth quarter of 2005.

Product revenue from the sales of MUSE in the United States for the year ended December 31, 2004 was $16.4 million compared to $19.0 million in 2003, a decrease of $2.5 million. International product revenue was $3.0 million for the year ended December 31, 2004, a decrease of $272,000 compared to 2003.

Worldwide product revenues from the sales of MUSE were $19.4 million in 2004, a decrease of $2.8 million, or 13%, from the worldwide sales of MUSE in 2003. The change in revenues was mainly due to decreased demand for MUSE. The launch of new PDE5 inhibitors and the associated direct-to-consumer advertising and aggressive sampling opportunities for all PDE5 inhibitors contributed to the decline in demand for MUSE. In addition, based on the fourth quarter 2004 demand for MUSE, as measured by independent third-party prescription data, we estimate purchases made by wholesalers ahead of our annual price increase in the fourth quarter of 2004, represented approximately 5 months of excess demand.

Given the stabilization of demand and the strategic buying in the fourth quarter of 2005, we anticipate worldwide revenues of MUSE in 2006 will remain consistent with those seen in 2005.

Cost of goods sold and manufacturing.

	(In thousands, except percentages) Years Ended December 31,			% Change Increase/(Decrease)	
	2005	2004	2003	05-04	04-03
Cost of goods sold and manufacturing	$ 11,018	$ 11,283	$ 10,993	(2)%	3%

Cost of goods sold and manufacturing (cost of goods sold) in the year ended December 31, 2005 decreased $265,000, or 2%, to $11.0 million, as compared to $11.3 million for the year ended December 31, 2004. We expensed approximately $6.8 million of manufacturing overhead costs in the year ended December 31, 2005, as compared to $5.9 million during the same period in 2004 as period costs because of excess manufacturing capacity at our New Jersey facility. This accounting treatment is based on the determination made during the 1998 restructuring that the manufacturing capacity of the New Jersey plant far exceeds the level of production required to meet estimated future market demand.

Additionally, in accordance with GAAP, in 1998 we reduced the carrying cost of alprostadil, the active ingredient in MUSE, and its component parts to zero due to excess quantities on hand at that time. Although the cost basis for alprostadil was reduced to zero, we continued to use this active ingredient as allowed by the FDA in the production of MUSE in 2004. By utilizing the inventory that had previously been written down to zero, we lowered our cost of sales for the year ended December 31, 2004 by $844,000. In the fourth quarter of 2004, we determined that we would likely not use the fully reserved raw materials inventory in future production. In the year ended December 31, 2005, we used component parts of this fully reserved inventory resulting in a favorable impact on our cost of goods sold of $76,000. We anticipate that cost of goods sold in 2006 will remain consistent with 2005 costs.

Cost of goods sold for 2004 was $11.3 million, as compared to $11.0 million for 2003, an increase of $290,000. As mentioned above, in 1998, we reduced the carrying cost of alprostadil, the active ingredient in MUSE, to zero due to excess quantities on hand at that time. We lowered our cost of sales for 2004 and 2003 by $844,000 and $1.2 million, respectively, by utilizing this previously written down inventory. The increase in cost of goods sold in 2004 as compared to 2003 was primarily due to use of recently purchased alprostadil that was expensed at its full cost of acquisition.

Research and development.

	(In thousands, except percentages) Years Ended December 31,			% Change Increase/(Decrease)	
	2005	2004	2003	05-04	04-03
Research and development	$ 17,005	$ 18,676	$ 7,724	(9)%	142%

Research and development expenses in the year ended December 31, 2005 were $17.0 million, as compared to $18.7 million in the year ended December 31, 2004. Increased clinical trial and project activity for ALISTA and Evamist resulted in incremental spending for these projects of $7.1 million in the year ended December 31, 2005, as compared to the same period last year. This increase was more than offset by a decrease of $2.8 million in avanafil, Testosterone MDTS and other related clinical trial and project spending, a decrease of $1.0 million in non-project related research and development expenses, primarily lower compensation expense due to reduced headcount, and $5.1 million in milestone and licensing fees which were incurred in 2004. During 2004, we entered into exclusive licensing agreements with a subsidiary of Acrux under

which we will develop and commercialize, in the United States, an estradiol spray (now known as Evamist) for the alleviation of the symptoms of menopause and a testosterone spray for the treatment of hypoactive sexual desire disorder in women. During the year ended December 31, 2004, we expensed a total of $3.3 million of licensing fees incurred under the terms of the agreements. In addition, during the year ended December 31, 2004, we initiated a Phase 2 clinical trial with avanafil, which we completed in 2005. Under the terms of our 2001 Development, Licensing and Supply Agreement with Tanabe, we expensed a $1.8 million licensing fee obligation to Tanabe in the year ended December 31, 2004. We intend to pay the entire obligation to Tanabe, totaling $2.0 million with imputed interest, in March 2006.

Research and development expenses for the year ended December 31, 2004 were $18.7 million, as compared to $7.7 million for the same period in 2003. During 2004, we expensed a total $3.3 million of licensing fees under the terms of the exclusive licensing agreements with a subsidiary of Acrux mentioned above. In addition, under the terms of our 2001 Development, Licensing and Supply Agreement with Tanabe, we expensed a $1.8 million milestone obligation to Tanabe in 2004. The expenses associated with the avanafil Phase 2 clinical trials in 2004 resulted in an additional $1.2 million expense. Increased clinical trial and project activity for

ALISTA, Evamist and Testosterone MDTS resulted in incremental spending for these projects of $1.9 million during 2004 as compared to 2003. Additionally, salary, benefit and consulting expenses increased in support of our ongoing projects.

We anticipate that our research and development expenses will decrease in 2006; however, based upon results of clinical trails or other new information, results of obtaining additional funding or as a result of entering into a collaborative arrangement, we may decide to increase research and development expenses at any time to pursue additional projects or studies. We do not expect to recognize revenue from sales of any new product candidates being developed through our research and development efforts for several years.

Selling, general and administrative.

	(In thousands, except percentages) Years Ended December 31,			% Change Increase	
	2005	2004	2003	05-04	04-03
Selling, general and administrative	$ 11,916	$ 11,730	$ 9,839	2%	19%

Selling, general and administrative expenses in the twelve months ended December 31, 2005 of $12.0 million were $186,000 higher than the same period last year due to several factors. In the first quarter of 2005, two of our largest wholesalers commenced charging us a distribution service fee based upon either the quantity of product purchased or sold by the respective wholesaler. We recorded expense of $229,000 for this distribution service fee in the year ended December 31, 2005 to selling, general and administrative expenses. We expect that these distribution service fees will continue into the future. In addition, we recorded $196,000 of incremental accounting and audit fees expense and $153,000 in other professional consulting fees in the year ended December 31, 2005 primarily related to compliance with the requirements of Sarbanes-Oxley. These increases were partially offset by a $384,000 reduction in MUSE advertising and promotion related expenses in the twelve months ended December 31, 2005 as compared to 2004.

Selling, general and administrative expenses for 2004 were $11.7 million as compared to $9.8 million for 2003, a $1.9 million increase. This increase was primarily due to an increase in spending for investor and public relations activities and marketing programs, as well as the absence of the reimbursement of previously incurred legal fees and other expenses related to the settlement of the Janssen Pharmaceutica arbitration claim in the third quarter of 2003.

We anticipate that our selling, general and administrative expenses will increase in 2006 due to sales and marketing efforts related to MUSE.

Interest income and expense.

Interest income for 2005 was $1.1 million, as compared to $622,000 for the year ended December 31, 2004. The increase is primarily due to an increase in our cash balances and related investment yields from the year ended December 31, 2004 to December 31, 2005. Interest expense for the year ended December 31, 2005 was $221,000 as compared to $143,000 during the same period last year. This interest expense is related to the Acrux milestone liabilities and Tanabe license fees and loan. The increased interest expense is primarily due to a higher loan balance outstanding for the Tanabe loan.

Interest income for 2004 was $622,000, as compared to $708,000 for 2003. Declining balances of cash, cash equivalents and available-for-sale securities contributed to the reduction in interest income. Interest expense of $143,000 in 2004 was related to the Acrux and Tanabe milestone liabilities. We did not have any interest expense in 2003.

Liquidity and Capital Resources

Cash. Unrestricted cash, cash equivalents and available-for-sale securities totaled $27.0 million at December 31, 2005, as compared to $29.8 million at December 31, 2004. The decrease is primarily due to the use of cash for operations and the purchase of our principal manufacturing facility, which was previously leased, partially offset by the March 15, 2005 sale of 6,250,000 shares of our common stock at a price of $3.40 per share, which provided us with net proceeds of $19.6 million.

Since inception, we have financed operations primarily from the issuance of equity securities and revenues. Through December 31, 2005, we raised $173.6 million from financing activities and had an accumulated deficit of $147.0 million at December 31, 2005.

Available-for-sale securities. We focus on liquidity and capital preservation in our investments in available-for-sale securities. We restrict our cash investments to:

Direct obligations of the United States Treasury;

Federal Agency securities which carry the direct or implied guarantee of the United States government; and

Corporate securities, including commercial paper, rated A1/P1 or better.

The weighted average maturity of our portfolio is not to exceed 18 months.

Accounts Receivable. Accounts receivable (net of allowance for doubtful accounts) at December 31, 2005 was $7.6 million, as compared to $9.5 million at December 31, 2004. The 20% decrease in the accounts receivable balance at December 31, 2005 is primarily due to decreased revenue and therefore receivables in the fourth quarter of 2005 as compared to the same period in 2004. Currently, we do not have any significant concerns related to accounts receivable or collections. As of February 15, 2006, we had collected 95% of the December 31, 2005 accounts receivable.

Liabilities. Total liabilities were $22.7 million at December 31, 2005, $986,000 lower than at December 31, 2004. The change in total liabilities is primarily due to the elimination of the $3.0 million accrued restructuring reserve as a result of our December 22, 2005 purchase of our previously leased manufacturing facilities in Lakewood, New Jersey partially offset by a $1.9 million increase in notes payable due to increased borrowings on the Tanabe line of credit.

We have entered into manufacturing agreements with suppliers to purchase raw materials. As of December 31, 2005, our remaining commitment under these agreements is to purchase a minimum of $3.8 million of product from 2006 through 2008. Should our inventory of raw materials exceed our future production needs, it may be necessary to write-off any excess inventory.

Operating Activities. Our operating activities used $21.1 and $22.7 million of cash during the years ended December 31, 2005 and 2004, respectively. During the year ended December 31, 2005, our net operating loss of $24.5 million was partially offset by a $1.8 million reduction in our accounts receivable, due to the collection of monies owed to us, and non-cash depreciation expense of $1.3 million. The cash used in 2004 can be attributed to our net operating loss of $21.6 million and a $7.0 million increase in our accounts receivable balance, partially offset by $3.6 million in increased accrued research, clinical and licensing fees primarily due to $2.9 million related to the future payment of milestone and licensing fees to Acrux and Tanabe, and $1.9 million in non-cash depreciation expense.

Investing Activities. Our investing activities provided $12.8 million and $13.5 million in cash during the year ended December 31, 2005 and 2004, respectively. The fluctuations from period to period are due primarily to the timing of purchases, sales and maturity of investment securities and the purchase of land and buildings for $7.1 million offset by the release of restricted cash of $3.3 million in 2005.

Financing Activities. Financing activities provided cash of $22.2 million and $4.4 million during the years ended December 31, 2005 and 2004, respectively. These amounts include the proceeds from the March 15, 2005 sale of 6,250,000 shares of our common stock at a price of $3.40 per share, providing us with net proceeds of $19.6 million in the year ended December 31, 2005, as well as the proceeds from the exercise of stock options, employee stock purchase plan (ESPP) purchases and borrowings under note arrangements in the year ended December 31, 2005 and 2004.

In the first quarter of 2004, we signed an agreement for a line of credit with Tanabe, allowing us to borrow up to $8.5 million to be used for the development of avanafil. The secured line of credit may be drawn upon quarterly and each quarterly borrowing will have a 48-month term and will bear interest at the annual rate of 2%. As of December 31, 2005, we had a long-term notes payable balance of $5.2 million and $3.3 million remaining available on the credit line. We borrowed an additional $2.0 million under this credit line during 2005.

On December 22, 2004, we filed a shelf registration statement on Form S-3 with the SEC, which allows us to offer and sell up to an aggregate of $50 million of common stock from time to time in one or more offerings. The terms of any such future offering would be established at the time of such offering. On February 22, 2005, we filed a prospectus supplement with the SEC relating to an underwritten public offering of 7,500,000 shares of common stock under the existing shelf registration statement and supplement thereto. On March 15, 2005, we sold 6,250,000 shares of our common stock at a price of $3.40 per share, providing us with net proceeds of $19.6 million.

On December 22, 2005, we purchased from our landlord our principal manufacturing facility, which was previously leased, for $7.1 million. The purchase price was funded in part by $3.3 million, which was being held by the landlord as cash collateral for renovations to the facility upon the termination of the lease and the remainder with cash. On January 4, 2006, we obtained a $5.4 million loan from Crown Bank, N.A. (Crown), secured by the land and buildings, among other assets, located at our principal

manufacturing facility and a $700,000 Certificate of Deposit held by Crown. The loan is payable over a 10-year term and the interest rate will be fixed at 8.25%, which is the prime rate plus 1% at the time of funding and then will be adjusted annually to a fixed rate for the year equal to the prime rate plus 1% with a floor of 7.5%.

The funding necessary to execute our business strategies is subject to numerous uncertainties, which may adversely affect our liquidity and capital resources. Completion of clinical trials may take several years or more, but the length of time generally varies substantially according to the type, complexity, novelty and intended use of a product candidate. It is also important to note that if a clinical candidate is identified, the further development of that candidate can be halted or abandoned at any time due to a number of factors. These factors include, but are not limited to, funding constraints, lack of efficacy or safety or change in market demand.

The nature and efforts required to develop our product candidates into commercially viable products include research to identify a clinical candidate, preclinical development, clinical testing, FDA approval and commercialization. This process is very costly and can take in excess of 10 years to complete for each product candidate. The duration and the cost of clinical trials may vary significantly over the life of a project as a result of differences arising during the clinical studies, including, among others, the following:

- we or the FDA may suspend trials;
- we may discover that a product candidate may cause harmful side effects or is not effective;
- patient recruitment may be slower than expected; and
- patients may drop out of the trials.

For each of our programs, we periodically assess the scientific progress and the merits of the programs to determine if continued research and development is economically viable. Certain of our programs have been terminated due to the lack of scientific progress and lack of prospects for ultimate commercialization. As such, the ultimate timeline and costs to commercialize a product cannot be accurately estimated.

Our product candidates have not yet achieved FDA regulatory approval, which is required before we can market them as therapeutic products. In order to achieve regulatory approval, the FDA must conclude that our clinical data establish safety and efficacy. The results from preclinical testing and early clinical trials may not be predictive of results in later clinical trials. It is possible for a candidate to show promising results in clinical trails, but subsequently fail to establish safety and efficacy data necessary to obtain regulatory approvals.

As a result of the uncertainties discussed above, among others, the duration and completion of our research and development projects are difficult to estimate and are subject to considerable variation. Our inability to complete our research and development projects in a timely manner or our failure to enter into collaborative agreements, when appropriate, could significantly increase our capital requirements and could adversely impact our liquidity. These uncertainties could force us to seek additional, external sources of financing from time to time in order to

continue with our business strategy. Our inability to raise capital, or to do so on terms reasonably acceptable to us, would jeopardize the future success of our business.

We may also be required to make further substantial expenditures if unforeseen difficulties arise in other areas of our business. In particular our future capital and additional funding requirements will depend upon numerous factors, including:

- the progress and costs of our research and development programs;
- the scope, timing and results of pre-clinical testing and clinical trials;
- patient recruitment and enrollment in current and future clinical trials;
- the costs involved in seeking regulatory approvals for our product candidates;
- the costs involved in filing and pursuing patent applications and enforcing patent claims;
- the establishment of collaborations and strategic alliances;
- the cost of manufacturing and commercialization activities and arrangements;

the results of operations;

demand for MUSE;

the cost, timing and outcome of regulatory reviews;

the rate of technological advances;

ongoing determinations of the potential commercial success of our products under development;

the level of resources devoted to sales and marketing capabilities; and

the activities of competitors.

We anticipate that our existing capital resources combined with anticipated future cash flows will be sufficient to support our operating needs into 2007. However, we anticipate that we will require additional funding to continue our research and product development programs, to conduct preclinical studies and trials, for operating expenses, to pursue regulatory approvals for our product candidates, for the costs involved in filing and prosecuting patent applications and enforcing or defending our patent claims, if any, and we may require additional funding to establish additional manufacturing and marketing capabilities in the future. In particular, we expect to make other substantial payments to Acrux and Tanabe in accordance with our agreements with them in connection with the licensing of certain compounds. These payments are based on certain development, regulatory and sales milestones. In addition, we are required to make royalty payments on any future product sales. We may seek to access the public or private equity markets whenever conditions are favorable. The sale of additional equity securities would result in additional dilution to our stockholders. We may also seek additional funding through strategic alliances and other financing mechanisms. We cannot assure you that adequate funding will be available on terms acceptable to us, if at all. If adequate funds are not available, we may be required to curtail significantly one or more of our research or development programs or obtain funds through arrangements with collaborators or others. This may require us to relinquish rights to certain of our technologies or product candidates. To the extent that we are unable to obtain third party funding for such expenses, we expect that increased expenses will result in increased losses from operations. We cannot assure you that we will successfully develop our products under development or that our products, if successfully developed, will generate revenues sufficient to enable us to earn a profit.

Overview of Contractual Obligations

		Payments Due by Period (in thousands)			
Contractual Obligations	**Total**	**Less than 1 year**	**1 - 3 years**	**3 - 5 years**	**More than 5 years**

Operating Leases (1)	$ 796	$ 735	$ 61			
Purchases (2)	3,825	1,530	2,295			
Notes Payable (3)	5,164		5,164			
Other Long Term Liabilities (4)	2,000	2,000				
Total	$ 11,785	$ 4,265	$ 7,520	$	$	

(1) We purchased our previously leased manufacturing facilities in Lakewood, New Jersey on December 22, 2005. In January 2000, we entered into a seven-year lease for our corporate headquarters in Mountain View, California, which expires in January 2007.

(2) In November 2002, we entered into a manufacturing agreement to purchase raw materials from a supplier beginning in 2003 and ending in 2008. Our remaining commitment under this agreement is to purchase a minimum total of $2.3 million of product from 2006 through 2008. In 2005, we purchased $765,000 of product, and in 2004 we purchased $762,000 of product from this supplier.

In January 2004, we entered into a manufacturing agreement to purchase raw materials from an additional supplier beginning in 2004 and ending in 2006. In February 2006, we amended the terms of this agreement to require the purchase of a minimum total of $1.5 million of product from 2006 through 2008. In 2005 we purchased $240,000 of product and in 2004, we purchased $475,000 of product.

(3) In the first quarter of 2004, we signed an agreement for a secured line of credit with Tanabe, allowing us to borrow up to $8.5 million to be used for the development of avanafil. The secured line of credit may be drawn upon quarterly and each quarterly borrowing will have a 48-month term and will bear interest at the annual rate of 2%. There are no financial covenants associated with

this secured line of credit. Under certain conditions, at our option, payments on this secured line of credit may be made, in whole or in part, in common stock. As of December 31, 2005, we have $3.3 million of available credit under this agreement.

(4) Other Long Term Liabilities includes $2.0 million for a licensing fee obligation, due under the terms of our 2001 Development, Licensing and Supply Agreement with Tanabe related to a Phase 2 clinical trial with avanafil initiated in the first quarter of 2004 and completed in 2005. We intend to pay this obligation in March 2006.

Recent Accounting Pronouncements

In November 2004, the FASB issued FAS No. 151, Inventory Costs, an amendment of ARB No. 43, Chapter 4. This Statement is meant to eliminate any differences existing between the FASB standards and the standards issued by the International Accounting Standards Board by clarifying that any abnormal idle facility expense, freight, handling costs and spoilage be recognized as current-period charges. This Statement is required to be adopted by VIVUS in the first quarter of 2006; however, early application is permitted. We do not expect the adoption of this Statement to have a material impact on results of operations, financial position or cash flows as we currently do expense a portion of our manufacturing overhead as period cost due to excess capacity.

In December 2004, the FASB issued revised statement No. 123 (FAS 123R), which requires companies to expense the estimated fair value of employee stock options and similar awards. In April 2005, the SEC announced the adoption of a new rule that amended the compliance dates for FAS 123R. The accounting provisions of FAS 123R will now be effective for the first quarter of fiscal 2006. We will adopt the provisions of FAS 123R using a modified prospective application. Under modified prospective application, FAS 123R, which provides certain changes to the method for valuing stock-based compensation among other changes, will apply to new awards and to awards that are outstanding on the effective date and are subsequently modified or cancelled. Further compensation expense for outstanding awards for which the requisite service had not been rendered as of the effective date will be recognized over the remaining service period using the compensation cost calculated for pro forma disclosure purposes under FAS 123. The impact of the adoption of FAS 123R cannot be predicted at this time because it will be depend on levels of share-based payments granted in the future. However, valuation of employee stock options under FAS 123R is similar to FAS 123, with minor exceptions. The impact on the results of operations and earnings per share had VIVUS adopted FAS 123, is described in the Stock Option Plans section of Note 1 to our Consolidated Financial Statements. Accordingly, the adoption of FAS 123R s fair value method will have a material impact on our results of operations, although it will have no impact on our overall financial position. FAS 123R also requires the benefits of tax deductions in excess of recognized compensation cost to be reported as a financing cash flow, rather than as an operating cash flow as required under current literature. This requirement will reduce net operating cash flows and increase net financing cash flows in periods after adoption. Due to timing of the release of FAS 123R, VIVUS has not yet completed the analysis of the ultimate impact that this new pronouncement will have on our results of operations. We are in the process of determining how the new method of valuing stock-based compensation as prescribed in FAS 123R will be applied to valuing stock-based awards granted after the effective date and the impact the recognition of compensation expense related to such awards will have on our consolidated financial statements. When we are required to expense stock option grants, it will reduce the attractiveness of granting stock options because of the additional expense associated with these grants. However, stock options are an important employee recruitment and retention tool, and we may not be able to attract and retain key personnel if we reduce the scope of our employee stock option program.

In March 2005, the SEC staff issued guidance on FAS 123R. Staff Accounting Bulletin No. 107 (SAB 107) was issued to assist preparers by simplifying some of the implementation challenges of FAS 123R while enhancing the information that investors receive. SAB 107 creates a framework that is premised on two overarching themes: (a) considerable judgment will be required by preparers to successfully implement FAS 123R, specifically when valuing employee stock options; and (b) reasonable individuals, acting in good faith, may conclude differently on the fair value of employee stock options. Key topics covered by SAB 107 include: (a) valuation models SAB 107 reinforces the flexibility allowed by FAS 123R to choose an option-pricing model that meets the standard s fair value measurement objective; (b) expected volatility the SAB provides guidance on when it would be appropriate to rely exclusively on either historical or implied volatility in estimating expected volatility; and (c) expected term the new guidance includes examples and some simplified approaches to determining the expected term under certain

circumstances. We will apply the principles of SAB 107 in conjunction with our adoption of FAS 123R.

In May 2005, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards No. 154, Accounting Changes and Error Corrections A Replacement of APB Opinion No. 20 and FASB Statement No. 3. FAS 154 requires retrospective application to prior periods financial statements for changes in accounting principle, unless it is impracticable to determine either the period-specific effects or the cumulative effect of the change. FAS 154 also requires that retrospective application of a change in accounting principle be limited to the direct effects of the change. Indirect effects of a change in accounting principle, such as a change in non-discretionary profit-sharing payments resulting from an accounting change, should be recognized in the

period of the accounting change. FAS 154 also requires that a change in depreciation, amortization, or depletion method for long-lived non-financial assets be accounted for as a change in accounting estimate affected by a change in accounting principle. FAS 154 is effective for accounting changes and corrections of errors made in fiscal years beginning after December 15, 2005. Early adoption is permitted for accounting changes and corrections of errors made in fiscal years beginning after the date this Statement is issued. We are required to adopt the provision of FAS 154, as applicable, beginning in fiscal 2006. We do not anticipate that the adoption of this statement will have a material impact on our results of operations or financial condition.

Off-Balance Sheet Arrangements

We have not entered into any off-balance sheet financing arrangements and have not established any special purpose entities. We have not guaranteed any debt or commitments of other entities or entered into any options on non-financial assets.

Dividend Policy

We have not paid any dividends since its inception and do not intend to declare or pay any dividends on our common stock in the foreseeable future. Declaration or payment of future dividends, if any, will be at the discretion of our Board of Directors after taking into account various factors, including our financial condition, operating results and current and anticipated cash needs.

Cautionary Note on Forward-Looking Statements

Our business is subject to significant risks, including but not limited to, the risks inherent in our research and development activities, including the successful completion of clinical trials, the lengthy, expensive and uncertain process of seeking regulatory approvals, uncertainties associated both with the potential infringement of patents and other intellectual property rights of third parties, and with obtaining and enforcing our own patents and patent rights, uncertainties regarding government reforms and of product pricing and reimbursement levels, technological change, competition, manufacturing uncertainties and dependence on third parties. Even if our product candidates appear promising at an early stage of development, they may not reach the market for numerous reasons. Such reasons include the possibilities that the product will be ineffective or unsafe during clinical trials, will fail to receive necessary regulatory approvals, will be difficult to manufacture on a large scale, will be uneconomical to market or will be precluded from commercialization by proprietary rights of third parties. For more information about the risks we face, see Item 1.A. Risk Factors included in this report.

Item 7a. ***Quantitative and Qualitative Disclosures about Market Risk***

The Securities and Exchange Commission s rule related to market risk disclosure requires that we describe and quantify potential material losses from market risk sensitive instruments attributable to reasonably possible market changes. Market risk sensitive instruments include all financial or commodity instruments and other financial instruments that are sensitive to future changes in interest rates, currency exchange rates, commodity prices or other market factors.

Interest Rate Risk

We are exposed to interest rate risk on our short-term investments. The primary objective of our investment activities is to preserve principal while at the same time maximizing yields without significantly increasing risk. To achieve this objective, we invest in highly liquid and high quality government and other debt securities. To minimize our exposure due to adverse shifts in interest rates, we invest in short-term securities and ensure that the maximum weighted average of our maturity of our investments does not exceed 18 months. If a 10% change in interest rates were to have occurred on December 31, 2005, this change would not have had a material effect on the fair value of our investment portfolio as of that date. Due to the short holding period of our investments, we have concluded that we do not have a material financial market risk exposure.

We are also exposed to interest rate risk on the $5.4 million loan from Crown Bank, N.A. obtained on January 4, 2006. The loan is payable over a 10-year term and the interest rate will be fixed at 8.25%, which is the prime rate plus 1% at the time of funding and then will be adjusted annually to a fixed rate for the year equal to the prime rate plus 1% with a floor of 7.5%.

Item 8. ***Financial Statements and Supplementary Data***

VIVUS, INC.

1. Index to Consolidated Financial Statements

The following financial statements are filed as part of this Report:

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders of VIVUS, Inc.

We have audited the accompanying consolidated balance sheet of VIVUS, Inc. as of December 31, 2005, and the related consolidated statements of operations and other comprehensive loss, stockholders equity and cash flows for the year ended December 31, 2005. In connection with our audits, we also have audited the 2005 data in financial statement schedule II. These financial statements and schedule are the responsibility of VIVUS, Inc. s management. Our responsibility is to express an opinion on these financial statements and schedule based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the consolidated financial statements audited by us present fairly, in all material respects, the consolidated financial position of VIVUS, Inc. at December 31, 2005, and the consolidated results of its operations and its cash flows for the year ended December 31, 2005, in conformity with U.S. generally accepted accounting principles. Also, in our opinion, the related financial statement schedule, when considered in relation to the basic financial statements taken as a whole, presents fairly in all material respects the information set forth therein.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of VIVUS, Inc. s internal control over financial reporting as of December 31, 2005, based on criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated February 10, 2006 expressed an unqualified opinion thereon.

/s/ ODENBERG, ULLAKKO, MURANISHI & CO. LLP

San Francisco, CA

February 10**,** 2006

The Board of Directors and Stockholders of VIVUS, Inc.

We have audited management s assessment, included in Management s Report on Internal Control Over Financial Reporting, included in Item 9A, that VIVUS, Inc. maintained effective internal control over financial reporting as of December 31, 2005, based on criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). VIVUS, Inc. s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on management s assessment and an opinion on the effectiveness of VIVUS, Inc. s internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, evaluating management s assessment, testing and evaluating the design and operating effectiveness of internal control, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company s internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company s internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company s assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, management s assessment that VIVUS, Inc. maintained effective internal control over financial reporting as of December 31, 2005, is fairly stated, in all material respects, based on the COSO criteria. Also, in our opinion, VIVUS, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2005, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheet of VIVUS, Inc. as of December 31, 2005, and the related consolidated statements of operations and other comprehensive loss, stockholders equity and cash flows for the year ended December 31, 2005 and our report dated February 10, 2006 expressed an unqualified opinion thereon.

/s/ ODENBERG, ULLAKKO, MURANISHI & CO. LLP

San Francisco, CA

February 10, 2006

The Board of Directors and Stockholders

VIVUS, Inc.:

We have audited the accompanying consolidated balance sheet of VIVUS, Inc. and subsidiaries as of December 31, 2004, and the related consolidated statements of operations and other comprehensive loss, stockholders equity, and cash flows for each of the years in the two-year period ended December 31, 2004. In connection with our audits, we also have audited the 2004 and 2003 data in financial statement schedule II. These consolidated financial statements and schedule are the responsibility of the Company s management. Our responsibility is to express an opinion on these consolidated financial statements and financial statement schedule based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of VIVUS, Inc. and subsidiaries as of December 31, 2004, and the results of their operations and their cash flows for each of the years in the two-year period ended December 31, 2004, in conformity with U.S. generally accepted accounting principles. Also in our opinion, the related financial statement schedule, when considered in relation to the basic consolidated financial statements taken as a whole, present fairly, in all material respects, the information set forth therein.

/s/ KPMG LLP
KPMG LLP

San Francisco, California
March 15, 2005

VIVUS, INC.

CONSOLIDATED BALANCE SHEETS
(In thousands, except par value)

	December 31	
	2005	**2004**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 22,236	$ 8,304
Available-for-sale securities	4,770	16,739
Accounts receivable (net of allowance for doubtful accounts of $202 and $104 at December 31, 2005 and 2004, respectively)	7,604	9,544
Inventories, net	4,504	3,855
Prepaid expenses and other assets	1,024	1,459
Total current assets	40,138	39,901
Property, plant and equipment, net	9,144	6,394
Restricted cash		3,324
Available-for-sale securities, non-current		4,770
Total assets	$ 49,282	$ 54,389
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 3,779	$ 3,120
Accrued product returns	3,016	3,211
Accrued research and clinical expenses	1,886	1,192
Accrued licensing fees	1,972	972
Accrued chargeback reserve	1,832	1,626
Accrued employee compensation and benefits	1,280	1,442
Income taxes payable	1,215	1,214
Accrued and other liabilities	1,589	1,658
Total current liabilities	16,569	14,435
Notes payable	5,164	3,239
Accrued restructuring reserve		3,021
Deferred revenue	948	1,110
Accrued licensing fees		1,862
Total liabilities	22,681	23,667
Commitments and contingencies		
Stockholders equity:		
Preferred stock; $1.00 par value; 5,000 shares authorized; no shares issued and outstanding at December 31, 2005 and 2004		
Common stock; $.001 par value; 200,000 shares authorized at December 31, 2005 and 2004; 44,642 shares issued and outstanding at December 31, 2005 and 38,127 at December 31, 2004	45	38
Additional paid-in capital	173,613	153,275
Accumulated other comprehensive loss	(30)	(48)
Accumulated deficit	(147,027)	(122,543)
Total stockholders equity	26,601	30,722
Total liabilities and stockholders equity	$ 49,282	$ 54,389

See accompanying notes to consolidated financial statements.

VIVUS, INC.

**CONSOLIDATED STATEMENTS OF OPERATIONS
AND OTHER COMPREHENSIVE LOSS
(In thousands, except per share data)**

	Year Ended December 31		
	2005	2004	2003
Revenue			
United States product, net	$ 11,697	$ 16,419	$ 18,953
International product	2,794	3,030	3,302
Other revenue	163	152	5,183
Total revenue	14,654	19,601	27,438
Operating expenses:			
Cost of goods sold	11,018	11,283	10,993
Research and development	17,005	18,676	7,724
Selling, general and administrative	11,916	11,730	9,839
Total operating expenses	39,939	41,689	28,556
Loss from operations	(25,285)	(22,088)	(1,118)
Interest and other income (expense):			
Interest income	1,094	622	708
Interest expense	(221)	(143)	
Other (expense) income	(47)	32	65
Loss before (provision) benefit for income taxes	(24,459)	(21,577)	(345)
(Provision) benefit for income taxes	(25)	(6)	319
Net loss	$ (24,484)	$ (21,583)	$ (26)
Other comprehensive loss:			
Unrealized gain (loss) on securities, net of taxes	18	(112)	(217)
Comprehensive loss	$ (24,466)	$ (21,695)	$ (243)
Net loss per share:			
Basic and diluted	$ (0.57)	$ (0.57)	$ (0.00)
Shares used in per share computation:			
Basic and diluted	43,272	38,010	35,884

See accompanying notes to consolidated financial statements.

VIVUS, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY
(In thousands)

	Common Stock		Additional Paid-In	Accumulated Other Comprehensive	Accumulated	
	Shares	Amount	Capital	Income (Loss)	Deficit	Total
Balances, December 31, 2002	32,999	$ 33	$ 135,005	$ 281	$ (100,934)	$ 34,385
Sale of common stock through employee stock purchase plan	108		325			325
Exercise of common stock options for cash	306		312			312
Stock compensation costs			39			39
Proceeds from private placement of common stock	4,375	5	17,500			17,505
Issue costs for private placement of common stock			(1,088)			(1,088)
Change in unrealized gain on securities, net of taxes				(217)		(217)
Net loss					(26)	(26)
Balances, December 31, 2003	37,788	38	152,093	64	(100,960)	51,235
Sale of common stock through employee stock purchase plan	84		283			283
Exercise of common stock options for cash	255		859			859
Stock compensation costs			40			40
Change in unrealized gain on securities, net of taxes				(112)		(112)
Net loss					(21,583)	(21,583)
Balances, December 31, 2004	38,127	38	153,275	(48)	(122,543)	30,722
Sale of common stock through employee stock purchase plan	120		277			277
Exercise of common stock options for cash	145		440			440
Stock compensation costs			44			44
Proceeds from private placement of common stock	6,250	7	21,243			21,250
Issue costs for private placement of common stock			(1,666)			(1,666)
Change in unrealized gain on securities, net of taxes				18		18
Net loss					(24,484)	(24,484)

Balances, December 31, 2005	44,642	$ 45	$ 173,613	$ (30)	$ (147,027)	$ 26,601	

See accompanying notes to consolidated financial statements.

VIVUS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	Year Ended December 31		
	2005	**2004**	**2003**
Cash flows from operating activities:			
Net loss	$ (24,484)	$ (21,583)	$ (26)
Adjustments to reconcile net loss to net cash provided by (used for) operating activities:			
Provision for doubtful accounts	98	36	(77)
Depreciation	1,341	1,936	2,074
Stock compensation costs	44	40	39
Loss (gain) on disposal of property and equipment	34	7	(26)
Changes in assets and liabilities:			
Accounts receivable	1,842	(6,957)	1,955
Inventories	(649)	(746)	(1,751)
Prepaid expenses and other assets	435	(351)	389
Accounts payable	659	203	1,051
Accrued product returns	(195)	189	742
Accrued research, clinical and licensing fees	(168)	3,568	(905)
Accrued chargeback reserve	206	682	36
Accrued employee compensation and benefits	(162)	193	120
Accrued and other liabilities	(111)	96	(1,752)
Net cash (used for) provided by operating activities	(21,110)	(22,687)	1,869
Cash flows from investing activities:			
Land and buildings purchase	(7,142)		
Other property and equipment purchases	(123)	(118)	(225)
Release of restricted cash	3,324		
Proceeds from sale of property and equipment		1	41
Investment purchases	(42,371)	(20,451)	(42,798)
Proceeds from sale/maturity of securities	59,128	34,081	24,860
Net cash provided by (used for) investing activities	12,816	13,513	(18,122)
Cash flows from financing activities:			
Borrowing under note agreements	1,925	3,239	
Exercise of common stock options	440	859	312
Sale of common stock through employee stock purchase plan	277	283	325
Net proceeds from issuance of common stock	19,584		16,417
Net cash provided by financing activities	22,226	4,381	17,054
Net increase (decrease) in cash and cash equivalents	13,932	(4,793)	801
Cash and cash equivalents:			
Beginning of year	8,304	13,097	12,296
End of year	$ 22,236	$ 8,304	$ 13,097
Supplemental cash flow disclosure:			
Interest paid	$ 80	$ 17	$
Income taxes paid (received)	$ 10	$ 13	$ (494)
Non-cash investing and financing activities:			
Release of restructuring reserve	$ (3,021)	$	$
Unrealized gain (loss) on securities	$ 18	$ (112)	$ (217)

See accompanying notes to consolidated financial statements.

VIVUS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 1. Business and Significant Accounting Policies

Business

VIVUS, Inc. is a specialty pharmaceutical company, incorporated in 1991, focused on the research, development and commercialization of products to restore sexual function in women and men. The Company s product pipeline includes four clinical stage product candidates, each of which targets an estimated existing or potential market in excess of $1 billion annually. Evamist™, currently in Phase 3 development, is the Company s product candidate to alleviate symptoms associated with menopause. Avanafil, which recently completed Phase 2 trials, is VIVUS phosphodiesterase type 5, or PDE5, inhibitor product candidate for the treatment of erectile dysfunction. ALISTA™, currently in Phase 2B trials, is the Company s product candidate for the treatment of female sexual arousal disorder. Testosterone MDTS®, which has completed a positive Phase 2 trial, is VIVUS product candidate to treat hypoactive sexual desire disorder. The Company also markets MUSE (alprostadil), a transurethral applicator used for treating erectile dysfunction, in the United States and internationally through distribution partners.

At December 31, 2005, the Company s accumulated deficit was approximately $147.0 million. Based on current plans, management expects to incur further losses for the foreseeable future. Management believes that the Company s cash, cash equivalents, and short-term investments at December 31, 2005, will be sufficient to meet the Company s obligations into 2007. Until the Company can generate sufficient levels of cash from its operations, the Company expects to continue to finance future cash needs primarily through proceeds from equity or debt financing, loans and collaborative agreements with corporate partners.

The Company primarily sells its products through wholesale channels in the United States. International sales are made only to the Company s international distributors. All transactions are denominated in United States dollars and the Company operates in a single segment reporting to the chief executive officer, based on the criteria of Statement of Financial Accounting Standards, or SFAS, No. 131, *Disclosures about Segments of an Enterprise and Related Information*.

Significant Accounting Policies

Principles of Consolidation

The consolidated financial statements include the accounts of VIVUS, Inc., VIVUS Real Estate LLC, a wholly owned subsidiary, VIVUS International Limited, a wholly owned subsidiary, and VIVUS Ireland Limited, VIVUS U.K. Limited and VIVUS B.V. Limited, wholly owned subsidiaries of VIVUS International Limited. All significant inter-company transactions and balances have been eliminated in consolidation. On February 20, 2004, VIVUS Ireland was officially dissolved. On December 31, 2005, VIVUS U.K. Limited became a dormant company.

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Cash and Cash Equivalents

The Company considers highly liquid investments with maturities from the date of purchase of three months or less to be cash equivalents. All cash equivalents are in money market funds and commercial paper. The fair value of the funds approximated cost.

Available-for-Sale Securities

Available-for-sale securities represent investments in debt securities that are stated at fair value. The difference between amortized cost (cost adjusted for amortization of premiums and accretion of discounts which are recognized as adjustments to interest income) and fair value, representing unrealized holding gains or losses, are recorded in Accumulated Other Comprehensive Income (Loss), a separate component of stockholders equity until realized. The change in unrealized gains (losses) on investments included in accumulated other comprehensive loss for 2005, 2004 and 2003, in thousands, are $18, $(112), and $(217), respectively.

The Company s policy is to record investments in debt securities as available-for-sale because the sale of such securities may be required prior to maturity. Any gains and losses on the sale of debt securities are determined on a specific identification basis and are included in interest and other income in the accompanying consolidated statements of operations and other comprehensive loss. Available-for-sale securities with original maturities beyond one year from the balance sheet date are classified as non-current.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of cash, cash equivalents, short-term investments and accounts receivable. The Company has established guidelines to limit its exposure to credit risk by placing investments with high credit quality financial institutions, diversifying its investment portfolio and placing investments with maturities that maintain safety and liquidity.

Inventories

Inventories are stated at the lower of cost (first-in, first-out basis) or market and consist of raw materials and component parts, work in process and finished goods. Cost includes material and conversion costs.

During the quarter ended September 30, 1998, the Company established significant reserves against its inventory to align with new estimates of expected future demand for MUSE. The Company had built up its inventory level prior to and after the launch of Viagra and had not anticipated the impact that Viagra would have on the demand for MUSE. The Company had anticipated sales to ultimately increase as a result of an expanding market for impotence products. Given the decline in demand for MUSE, in 1998 the Company recorded reserves of $16.0 million related to excess raw materials and future inventory purchase commitments for raw materials.

As of December 31, 2005, the remaining inventory reserve balance is $3.8 million. This remaining balance is related to the raw materials and component parts inventory that the Company previously estimated would not be used.

Some portion of the fully reserved inventory has been used in production. The Company used $76,000, $844,000 and $1.2 million of its fully reserved inventory in 2005, 2004 and 2003, respectively. The fully reserved inventory is charged to cost of goods sold at a zero basis when used, which has a favorable impact on gross profit. In the fourth quarter of 2004, the Company determined that it would likely not use the fully reserved raw materials inventory in future production. In the first quarter of 2005, the Company determined that it likely would continue to use some portion of the fully reserved component parts in production. The original cost of the fully reserved inventory related to component parts is $934,000 as of December 31, 2005.

Prepaid Expenses and Other Assets

Prepaid expenses and other assets generally consist of deposits and prepayments for future services. Prepayments are expensed when the services are received.

Property, Plant and Equipment

Property, plant and equipment is stated at cost and includes land, buildings, building improvements, machinery and equipment, computers and software, and furniture and fixtures. For financial reporting, depreciation is computed using the straight-line method over estimated useful lives of twenty years for buildings, and two to seven years for machinery and equipment, computers and software, and furniture and fixtures. Building improvements are amortized using the straight-line method over the estimated useful lives. Expenditures for repairs and maintenance, which do not extend the useful life of the property and equipment, are expensed as incurred. Upon retirement, the asset cost and related accumulated depreciation are relieved from the accompanying consolidated financial statements. Gains and losses associated with dispositions or impairment of equipment, and leasehold improvements are reflected as a component of other income, net in the accompanying consolidated statements of operations and other comprehensive loss.

In accordance with SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*, long-lived assets, such as property, plant and equipment, are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to an estimate of undiscounted future cash flows expected to be generated by the asset. If the carrying amount of the asset exceeds its estimated future cash flows, an impairment charge is recognized by the amount by which the carrying amount of the asset exceeds the fair value of the asset. Assets to be disposed of would be separately presented in the balance sheet and reported at the lower of the carrying amount or fair value less costs to sell, and are no longer depreciated. The assets and liabilities of a disposed group classified as held for sale would be presented separately in the

appropriate asset and liability sections of the balance sheet. The Company believes the future cash flows to be received from the long-lived assets will exceed the assets carrying value, and accordingly the Company has not recognized any impairment losses through December 31, 2005.

Restricted Cash

The Company issued an irrevocable standby letter of credit for $3.3 million during the fourth quarter of 2000, in connection with its previously leased manufacturing facilities. On December 22, 2005, the Company purchased this facility from its landlord and the standby letter of credit was cancelled and the restricted cash was released to the Company as part of this transaction.

Fair Value of Financial Instruments

Financial instruments, including cash and cash equivalents, accounts receivable, accounts payable, and accrued liabilities, are carried at cost, which management believes approximates fair value because of the short-term maturity of these instruments.

Revenue Recognition

The Company recognizes revenue when the following four criteria are met:

persuasive evidence of an arrangement exists;

shipment has occurred;

the sales price is fixed or determinable; and

collectibility is reasonably assured.

The Company recognizes revenue upon shipment when title passes to the customer and risk of loss is transferred to the customer. The Company does not have any post shipment obligations.

United States

The Company primarily sells its products through the wholesale channel in the United States. The Company provides for discounts, rebates, returns and other adjustments in the same period the related product sales are recorded. Provisions for discounts, rebates, returns and other adjustments are based upon analysis of historical data. Each period the Company reviews its reserves for discounts, rebates, returns and other adjustments based on data available at that time. Any adjustment to these reserves results in charges to the amount of product sales revenue recognized in the period.

International

The Company has supply agreements with Meda AB to market and distribute MUSE® internationally in some Member States of the European Union. In Canada, the Company has entered into a license and supply agreement with Paladin Labs, Inc. for the marketing and distribution of MUSE. Sales to the Company s distribution partner, who supplies MUSE in the European marketplace, for 2005, 2004 and 2003 were 93.4 %, 96.7%, and 92.1% of international sales, respectively. The balance of international sales was made to the Company s Canadian distribution partner.

The Company invoices its international distributors based on an agreed transfer price per unit, which is subject to revision based on contractual formulas upon quarterly reconciliations. Final pricing for product shipments to international distributors is subject to contractual formulas based on the distributor s net realized price to its customers. The Company recognizes additional revenue, if any, upon finalization of pricing with its international distributors. International distributors generally do not have the right to return products unless the products are damaged or defective.

The Company initially recorded $1.5 million of unearned revenue related to an upfront payment in accordance with the international supply agreement signed with Meda AB in September 2002. This amount is being recognized as income ratably over the term of the supply agreement. Through December 31, 2005, $500,000 has been recognized as revenue.

In 2003, the Company recorded other revenue of $5.0 million due to the resolution of the Company s arbitration claim against Janssen Pharmaceutica with the American Arbitration Association related to payments owing to VIVUS under a previously terminated distribution agreement between the companies. $3.7 million represents amounts received from Janssen Pharmaceutica under the arbitration award. The remaining $1.3 million results from recognizing Janssen Pharmaceutica related revenue that was previously deferred pending the outcome of the arbitration.

In November 2004, the Company recorded $125,000 of unearned revenue related to an upfront licensing payment in accordance with an amendment to its international supply and distribution agreement with Paladin Labs, Inc. This amount is being recognized as income ratably over the term of the supply and distribution agreement. Through December 31, 2005, $15,000 has been recognized as revenue.

Advertising and Sales Promotion expenses

Advertising and sales promotion expenses are charged to expense as incurred. The Company spent $801,000 in 2005, $1.2 million in 2004, and $821,000 in 2003 on advertising and sales promotion costs related to its marketed product, MUSE.

Shipping and Handling Costs

Shipping costs included in Selling, General and Administrative for 2005, 2004 and 2003, in thousands, are $218, $200, and $215, respectively. Handling costs included in Cost of Goods Sold for 2005, 2004, and 2003, in thousands, are $277, $332, and $342, respectively.

Research and Development Expenses

Research and development (R&D) expenses include license fees, related compensation, contractor fees, facilities costs, administrative expenses and clinical trials at other companies and research institutions under agreements, which are generally cancelable, among other related research and development costs. All such costs are charged to R&D expense as incurred. The Company reviews and accrues clinical trials and other R&D expense based on work performed, which relies on estimates of total costs incurred based on patient enrollment, completion of studies and other events. The Company follows this method since reasonably dependable estimates of the costs applicable to various stages of a research agreement or clinical trial can be made. Accrued clinical costs and other R&D expenses are subject to revisions as work progresses to completion. Revisions are charged to expense in the period in which the facts that give rise to the revision become known.

Product Returns

The Company has estimated reserves for product returns from wholesalers, hospitals and pharmacies. VIVUS estimates its reserves by utilizing historical information and data obtained from external sources. The Company records reserves for anticipated returns of expired or damaged product in the United States. VIVUS follows this method since reasonably dependable estimates of product returns can be made based on historical experience. Revisions in returns estimates are charged to income in the period in which the facts that give rise to the revision become known. There is no right-of-return on product sold internationally subsequent to shipment; thus, no returns reserve is needed. The Company routinely assesses its experience with product returns and adjusts the reserves accordingly. If actual product returns are greater than VIVUS estimates, additional reserves may be required.

Rebates and Sales Reserves

The Company has estimated reserves for government chargebacks for goods purchased by certain Federal government organizations including the Veterans Administration, Medicaid rebates to states for goods purchased by patients covered by Medicaid, other rebate programs and cash discounts for prompt payment. VIVUS estimates its reserves by utilizing historical information and data obtained from external sources. In estimating government chargeback reserves, VIVUS analyzes actual chargeback amounts and applies historical chargeback rates to estimates of the quantity of units sold subject to chargebacks. In estimating Medicaid and other rebates, the historical rebate percentage is used to estimate future rebates. Effective January 1, 2006, MUSE will no longer qualify for Medicaid reimbursement, which the Company does not believe will have a significant impact to its business. For qualified customers, VIVUS grants payment terms of 2%, net 30 days. Allowances for cash discounts are estimated based upon the amount of trade accounts receivable subject to the cash discounts. VIVUS routinely assesses its experience with cash discounts, Medicaid and other rebates and government chargebacks and adjusts the reserves accordingly. If actual government chargebacks, Medicaid rebates, rebate and cash discounts are greater than VIVUS estimates, additional reserves may be required.

Stock Option Plans

The Company applies the intrinsic-value-based method of accounting prescribed by Accounting Principles Board, or APB, Opinion No. 25, *Accounting for Stock Issued to Employees,* and related interpretations including Financial Accounting Standards Board, or FASB, Interpretation No. 44, *Accounting for Certain Transactions involving Stock Compensation, an Interpretation of APB Opinion No. 25,* issued in March 2000, to account for its fixed-plan stock options. Under this method, compensation expense is recorded on the date of the grant only if the current market price of the underlying stock exceeded the exercise price. FAS No. 123, *Accounting for Stock Based Compensation,* established accounting and disclosure requirements using a fair-value-based method of accounting for stock-based employee compensation plans. As allowed by FAS No. 123, the Company has elected to continue to apply the intrinsic-value-based method of accounting described above, and has adopted only the disclosure requirements of FAS No. 123. The following table illustrates the effect on the net loss if the fair-value-based method has been applied to all outstanding and unvested awards in each period.

	2005	2004	2003
	(In thousands, except per share data)		
Net loss, as reported	$ (24,484)	$ (21,583)	$ (26)
Deduct total stock-based employee compensation expense determined under fair-value-based method for all rewards, net of tax	(1,768)	(1,970)	(1,763)
Pro forma net loss	$ (26,252)	$ (23,553)	$ (1,789)
Net loss per share, as reported:			
Basic and diluted	$ (0.57)	$ (0.57)	$ (0.00)
Pro forma net loss per share:			
Basic and diluted	$ (0.61)	$ (0.62)	$ (0.05)

The weighted-average fair value of options granted in 2005, 2004 and 2003 was $2.19, $3.17 and $2.63, respectively.

The fair value of each option grant is estimated on the date of grant using the Black-Scholes option-pricing model with the following weighted-average assumptions used for grants in 2005, 2004 and 2003: no dividend yield, expected volatility of 53%, 66% and 65%, respectively, risk-free interest rates of 4%, between 2% to 4% and 1% to 4%, respectively and an expected life of 5 years for all years.

In December 2004, the FASB issued revised statement No. 123 (FAS 123R), which requires companies to expense the estimated fair value of employee stock options and similar awards. In April 2005, the SEC announced the adoption of a new rule that amended the compliance dates for FAS 123R. The accounting provisions of FAS 123R will now be effective for the first quarter of fiscal 2006. The Company will adopt the provisions of FAS 123R using a modified prospective application. Under modified prospective application, FAS 123R, which provides certain changes to the method for valuing stock-based compensation among other changes, will apply to new awards and to awards that are outstanding on the effective date and are subsequently modified or cancelled. Further compensation expense for outstanding awards for which the requisite service had not been rendered as of the effective date will be recognized over the remaining service period using the compensation cost calculated for pro forma disclosure purposes under FAS 123. The impact of the adoption of FAS 123R cannot be predicted at this time because it will be depend on levels of share-based payments granted in the future. However, valuation of employee stock options under FAS 123R is similar to FAS 123, with minor exceptions. The impact on the results of operations and earnings per share had VIVUS adopted FAS 123, is described in the table above. Accordingly, the adoption of FAS 123R s fair value method will have a material impact on the Company s results of operations, although it will have no impact on its overall financial position. FAS 123R also requires the benefits of tax deductions in excess of recognized compensation cost to be reported as a financing cash flow, rather than as an operating cash flow as required under current literature. This requirement will reduce net operating cash flows and increase net financing cash flows in periods after adoption. Due to timing of the release of FAS 123R, VIVUS has not yet completed the analysis of the ultimate impact that this new pronouncement will have on its results of operations.

Effective February 28, 2005, the vesting of the 359,682 outstanding stock options granted on January 21, 2002, of which 82,479 were unvested options, was accelerated to that date. The options were originally scheduled to vest during the period from January 2002 to January 2012. On the accelerated vesting date, the per share market value of VIVUS stock of $3.98 was less than the strike price of the options, which was $8.08 per share. When considering this action, the Compensation Committee took into account that accelerating the vesting of these out-of-the money options prior to when the Company expected to adopt FAS 123R, would further reduce the amount of compensation expense that the Company would be required to record in 2006 and beyond as a result of the previously granted equity incentive awards. In addition, by accelerating these options before the implementation of FAS 123R, the expenses associated with the implementation of FAS 123R will be lower in future periods. The acceleration of these out-of-the money options did not cause any additional compensation expense in 2005. Under FAS 123R, the compensation expense associated with these out-of-the-money options would have been significant.

Income Taxes

Income taxes are accounted for under the asset and liability method. The realization of deferred tax assets and liabilities is based on historical tax positions and expectations about future taxable income. Deferred income tax assets and liabilities are computed for differences between the financial statement carrying amount and tax basis of assets and liabilities based on enacted tax laws and rates applicable to the period in which differences are expected to be recovered or settled. Valuation allowances are established, when necessary, to reduce deferred tax assets to amounts that are more likely than not to be realized.

License Agreements

The Company has obtained rights to patented technologies under several licensing agreements. Non-refundable licensing payments made on technologies that are yet to be proven are expensed to research and development. Royalties paid associated with existing products are expensed to cost of goods sold when the liability is generated upon sale of product.

Net (Loss) Income Per Share

Basic (loss) earnings per share, or EPS, is computed using the weighted average number of common shares outstanding during the periods. Diluted EPS is based on the weighted average number of common and common equivalent shares, which represent shares that may be issued in the future upon the exercise of outstanding stock options under the treasury stock method. The computation of basic and diluted EPS for the years ended December 31, 2005, 2004 and 2003 are as follows:

	2005	2004	2003
	(In thousands, except per share data)		
Net loss	$ (24,484)	$ (21,583)	$ (26)
Net loss per share basic	$ (.57)	$ (.57)	$ (.00)
Effect of dilutive securities (stock options)			
Net loss per share diluted	$ (.57)	$ (.57)	$ (.00)
Shares used in the computation of net loss per share basic	43,272	38,010	35,884
Effect of dilutive securities (stock options)			
Diluted shares	43,272	38,010	35,884

Potentially dilutive options outstanding of 161,212, 696,815 and 481,437 at December 31, 2005, 2004 and 2003, respectively, are excluded from the computation of diluted EPS for 2005, 2004 and 2003 because the effect would have been antidilutive.

Future Accounting Requirements

In November 2004, the FASB issued FAS No. 151, Inventory Costs, an amendment of ARB No. 43, Chapter 4. This Statement is meant to eliminate any differences existing between the FASB standards and the standards issued by the International Accounting Standards Board by clarifying that any abnormal idle facility expense, freight, handling costs and spoilage be recognized as current-period charges. This Statement is required to be adopted by the Company in the first quarter of 2006; however, early application is permitted. The Company does not expect the adoption of this Statement to have a material impact on results of operations, financial position or cash flows as it currently does expense a portion of its manufacturing overhead as period cost due to excess capacity.

In December 2004, the FASB issued revised statement No. 123 (FAS 123R), which requires companies to expense the estimated fair value of employee stock options and similar awards. In April 2005, the SEC announced the adoption of a new rule that amended the compliance dates for FAS 123R. The accounting provisions of FAS 123R will now be effective for the first quarter of fiscal 2006. The Company will adopt the provisions of FAS 123R using a modified prospective application. Under modified prospective application, FAS 123R, which provides certain changes to the method for valuing stock-based compensation among other changes, will apply to new awards and to awards that are outstanding on the effective date and are subsequently modified or cancelled. Further compensation expense for outstanding awards for which the requisite service had not been rendered as of the effective date will be recognized over the remaining service period using the compensation cost calculated for pro forma disclosure purposes under FAS 123. The impact of the adoption of FAS 123R cannot be predicted at this time because it will be depend on levels of share-based payments granted in the future. However, valuation of employee stock options under FAS 123R is similar to FAS 123, with minor exceptions. The impact on the results of operations and earnings per share had the Company adopted FAS 123, is described in the Stock Option Plans section of Note 1 above. Accordingly, the adoption of FAS 123R s fair value method will have a material impact on the Company s results of operations, although it will have no impact on the Company s overall financial position. FAS 123R also requires the benefits of tax deductions in excess of recognized compensation cost to be reported as a financing cash flow, rather than as an operating cash flow as required under current literature. This requirement will reduce net operating cash flows and increase net financing cash flows in periods after adoption. Due to timing of the release of FAS 123R, the Company has not yet completed the analysis of the ultimate impact that this new pronouncement will have on the results of operations. The Company is in the process of determining how the new method of valuing stock-based compensation as prescribed in FAS 123R will be applied to valuing stock-based awards granted after the effective date and the impact the recognition of compensation expense related to such awards will have on its consolidated financial statements.

In March 2005, the SEC staff issued guidance on FAS 123R. Staff Accounting Bulletin No. 107 (SAB 107) was issued to assist preparers by simplifying some of the implementation challenges of FAS 123R while enhancing the information that investors receive. SAB 107 creates a framework that is premised on two overarching themes: (a) considerable judgment will be required by preparers to successfully implement FAS 123R, specifically when valuing employee stock options; and (b) reasonable individuals, acting in good faith, may conclude differently on the fair value of employee stock options. Key topics covered by SAB 107 include: (a) valuation models SAB 107 reinforces the flexibility allowed by FAS 123R to choose an option-pricing model that meets the standard s fair

value measurement objective; (b) expected volatility the SAB provides guidance on when it would be appropriate to rely exclusively on either historical or implied volatility in estimating expected volatility; and (c) expected term the new guidance includes examples and some simplified approaches to determining the expected term under certain circumstances. The Company will apply the principles of SAB 107 in conjunction with its adoption of FAS 123R.

In May 2005, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards No. 154, Accounting Changes and Error Corrections A Replacement of APB Opinion No. 20 and FASB Statement No. 3. FAS 154 requires retrospective application to prior periods financial statements for changes in accounting principle, unless it is impracticable to determine either the period-specific effects or the cumulative effect of the change. FAS 154 also requires that retrospective application of a change in accounting principle be limited to the direct effects of the change. Indirect effects of a change in accounting principle, such as a change in non-discretionary profit-sharing payments resulting from an accounting change, should be recognized in the period of the accounting change. FAS 154 also requires that a change in depreciation, amortization, or depletion method for long-lived non-financial assets be accounted for as a change in accounting estimate affected by a change in accounting principle. FAS 154 is effective for accounting changes and corrections of errors made in fiscal years beginning after December 15, 2005. Early adoption is permitted for accounting changes and corrections of errors made in fiscal years beginning after the date this Statement is issued. The Company is required to adopt the provision of FAS 154, as applicable, beginning in fiscal 2006. The Company does not anticipate that the adoption of this statement will have a material impact on its results of operations or financial condition.

Reclassifications

Certain reclassifications have been made to the Company s 2004 and 2003 consolidated financial statements to conform to the current period presentations.

Note 2. Available-for-Sale Securities

The fair value and the amortized cost of available-for-sale securities at December 31, 2005 and 2004 are presented in the tables that follow. Fair values are based on quoted market prices obtained from an independent broker. For each category of investment securities, the table presents gross unrealized holding gains and losses.

As of December 31, 2005 (in thousands):

	Amortized Cost	Fair Market Value	Unrealized Holding Gains	Unrealized Holding Losses
United States government securities	$ 4,400	$ 4,370	$	$ (30)
Corporate debt	400	400		
Total	4,800	4,770		(30)
Amount classified as short-term	(4,800)	(4,770)		30
Amount classified as long-term	$	$	$	$

As of December 31, 2004 (in thousands):

	Amortized Cost	Fair Market Value	Unrealized Holding Gains	Unrealized Holding Losses
United States government securities	$ 16,646	$ 16,600	$	$ (46)
Corporate debt	4,911	4,909		(2)
Total	21,557	21,509		(48)
Amount classified as short-term	(16,756)	(16,739)		17
Amount classified as long-term	$ 4,801	$ 4,770	$	$ (31)

Note 3. Inventories

Inventory balances, net of reserves of $3.8 million and $3.9 million as of December 31, 2005 and 2004, respectively, consist of (in thousands):

	2005	2004
Raw materials and component parts	$ 3,666	$ 3,260
Work in process	33	22
Finished goods	805	573
Inventory, net	$ 4,504	$ 3,855

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As noted above, the Company has recorded significant reserves against the carrying value of its inventory of raw material and certain component parts. The reserves relate primarily to inventory that the Company previously estimated would not be used. Some portion of the fully reserved inventory has been used in production. The Company used $76,000 and $844,000 of its fully reserved inventory in 2005 and 2004, respectively. The fully reserved inventory is charged to cost of goods sold at a zero basis when used, which has a favorable impact on gross profit. In the fourth quarter of 2004, the Company determined that it would likely not use the fully reserved raw materials inventory in future production. In the first quarter of 2005, the Company determined that it likely would continue to use some portion of the fully reserved component parts in production. The original cost of the fully reserved inventory related to component parts is $934,000 as of December 31, 2005.

Note 4. Property, Plant and Equipment

Property, plant and equipment as of December 31, 2005 and 2004, respectively, consist of (in thousands):

	2005	2004
Land	$ 901	$
Buildings	3,102	
Machinery and equipment	18,161	18,160
Computers and software	2,464	2,504
Furniture and fixtures	1,204	1,254
Building improvements	11,951	11,947
	37,783	33,865
Accumulated depreciation	(28,639)	(27,471)
Property and equipment, net	$ 9,144	$ 6,394

The Company purchased its previously leased manufacturing facilities in Lakewood, New Jersey on December 22, 2005. For the years ended December 31, 2005, 2004 and 2003, depreciation expense, in thousands, was $1,341, $1,936 and $2,074, respectively.

Note 5. Notes Payable

In the first quarter of 2004, the Company signed an agreement for a secured line of credit with Tanabe Holding America, Inc., a subsidiary of Tanabe Seiyaku Co., Ltd., or Tanabe, allowing it to borrow up to $8.5 million to be used for the development of avanafil, an erectile dysfunction compound that has completed Phase 2 clinical trials. The secured line of credit may be drawn upon quarterly and each quarterly borrowing has a 48-month term and bears interest at the annual rate of 2%. There are no financial covenants associated with this secured line of credit. Under certain conditions, at the Company s option, payments on this secured line of credit may be made, in whole or in part, in common stock. As of December 31, 2005, VIVUS had long-term notes payable to Tanabe of $5.2 million, and $3.3 million of available credit under this agreement. All the assets of the Company, except the land and buildings, serve as collateral for this line of credit.

The amount of each quarterly borrowing and its due date are (in thousands):

Date of Note	Amount of Note	Due Date
March 31, 2004	$ 315	March 31, 2008

June 30, 2004		883	June 30, 2008
September 30, 2004		1,007	September 30, 2008
December 31, 2004		1,034	December 31, 2008
March 31, 2005		700	March 31, 2009
June 30, 2005		417	June 30, 2009
September 30, 2005		573	September 30, 2009
December 31, 2005		235	December 31, 2009
Total	$	5,164	

Note 6. Restructuring and Related Charges

In 1998, the Company restructured its operations and recorded related costs and write-downs in accordance with Emerging Issues Task Force, or EITF, 94-3. The property write-downs were calculated in accordance with the provisions of SFAS No. 121 and represent the excess of the carrying value of property and equipment, primarily the Company s New Jersey manufacturing leaseholds and equipment, over the projected future discounted cash flows for the Company.

Restructuring reserve at December 31, 2005 and 2004 was $0, and $3.0 million, respectively.

The balance in the restructuring reserve was related to the restoration liability for the Company s previously leased manufacturing facilities. On December 22, 2005, the Company purchased from its landlord its principal manufacturing facility, which was previously leased, for $7.1 million. The purchase price was funded in part by $3.3 million, which was being held by the landlord as cash collateral for renovations to the facility upon the termination of the lease and the remainder with cash. As a result, the $3.0 million restructuring reserve, which was related to the restoration liability on this facility, was eliminated and recorded as an adjustment against the purchase price of the building in December 2005.

Note 7. Stockholders Equity

Common Stock

The Company is authorized to issue 200 million shares of common stock. As of December 31, 2005 and 2004, there were 44,641,591 and 38,126,962 shares, respectively, issued and outstanding.

On December 22, 2004, the Company filed a shelf registration statement on Form S-3 with the SEC, which allows it to offer and sell up to an aggregate of $50 million of common stock from time to time in one or more offerings. The terms of any such future offering would be established at the time of such offering. On February 22, 2005, the Company filed a prospectus supplement with the SEC relating to an underwritten public offering of 7,500,000 shares of common stock under the existing shelf registration statement and supplement thereto. On March 15, 2005, VIVUS sold 6,250,000 shares of its common stock at a price of $3.40 per share, providing the Company with net proceeds of $19.6 million.

Preferred Stock

The Company is authorized to issue 5 million shares of undesignated preferred stock with a par value of $1.00 per share. As of December 31, 2005 and 2004, there are no preferred shares issued or outstanding. The Company may issue shares of preferred stock in the future, without stockholder approval, upon such terms as the Company s management and Board of Directors may determine.

Note 8. Stock Option and Purchase Plans

Stock Option Plan

Under the 2001 Stock Option Plan, or the 2001 Plan, which was approved by the stockholders at the annual meeting held on June 5, 2002, the Company may grant incentive or non-statutory stock options or stock purchase rights, or SPRs. The maximum aggregate number of shares that

may be optioned and sold under the 2001 Plan is 1,000,000 shares plus (a) any shares that have been reserved but not issued under the Company s 1991 Incentive Stock Option Plan, or the 1991 Plan; (b) any shares returned to the 1991 Plan as a result of termination of options or repurchase of shares issued under the 1991 Plan; and (c) an annual increase to be added on the first day of the Company s fiscal year beginning 2003, equal to the lesser of (i) 1,000,000 shares, (ii) 2.5% of the outstanding shares on such date, or (iii) a lesser amount determined by the Board. The 2001 Plan allows the Company to grant incentive stock options to employees at not less than 100% of the fair market value of the stock (110% of fair market value for individuals who control more than 10% of the Company stock) at the date of grant, as determined by the Board of Directors. The 2001 Plan allows the Company to grant non-statutory stock options to employees, directors and consultants at a price to be determined by the Board of Directors. The term of the option is determined by the Board of Directors on the date of grant but shall not be longer than ten years. The 2001 Plan allows the Company to grant SPRs to employees and consultants. Sales of stock under SPRs are made pursuant to restricted stock purchase agreements containing provisions established by the Board of Directors. The Company has a right, but not the obligation, to repurchase the shares at the original sale price, which expires at a rate to be determined by the Board of Directors. As of December 31, 2005, no SPRs have been granted under the 2001 Plan.

Under the 2001 Plan, non-employee directors will receive an option to purchase 32,000 shares of common stock when they join the Board of Directors. These options vest 25% after one year and 25% annually thereafter. Each non-employee director shall automatically receive an option to purchase 8,000 shares of the Company s common stock annually upon their reelection and these options are fully exercisable ratably over eight months. Non-employee directors are also eligible to receive additional stock option grants.

Details of option activity under these plans are as follows:

	Number of Shares	Weighted-Average Exercise Price
Outstanding, December 31, 2002	3,671,875	$ 4.16
Granted	642,526	4.04
Exercised	(306,631)	1.02
Cancelled	(31,344)	4.95
Outstanding, December 31, 2003	3,976,426	$ 4.38
Granted	868,126	4.82
Exercised	(251,212)	3.41
Cancelled	(478,555)	4.14
Outstanding, December 31, 2004	4,114,785	$ 4.56
Granted	1,132,178	3.76
Exercised	(144,523)	3.05
Cancelled	(697,776)	5.11
Outstanding, December 31, 2005	4,404,664	$ 4.31

Options Outstanding					Options Exercisable		
Range of Exercise Prices		Number Outstanding at December 31, 2005	Weighted-Average Remaining Contractual Life	Weighted-Average Exercise Price	Number Exercisable December 31, 2005	Weighted-Average Exercise Price
$2.00	$3.73	1,502,643	5.8 years	$ 3.14	890,293	$ 2.81
$3.75	$4.41	1,491,089	6.0 years	$ 4.07	1,032,772	$ 4.04
$4.50	$8.08	1,410,932	6.6 years	$ 5.83	1,062,016	$ 6.09
$2.00	$8.08	4,404,664	6.1 years	$ 4.31	2,985,081	$ 4.40

At December 31, 2005, 1,710,254 options remain available for grant.

During 2005, options to purchase 35,000 shares of common stock were granted to research consultants. The fair value of the options was estimated to be $68,000 on the date of grant using the Black-Scholes option-pricing model with the following assumptions: no dividend yield, expected volatility ranging from 49% to 50%, risk-free interest rate ranging from 3.49% to 4.12% and an expected life of 5 to 10 years. In the year ended December 31, 2005, the Company recorded $41,000 of compensation related to these grants to research and development expense.

During 2004, an option to purchase 15,000 shares of common stock was granted to a research consultant. The fair value of the option was estimated to be $41,000 on the date of grant using the Black-Scholes option-pricing model with the following assumptions: no dividend yield, expected volatility of 46%, risk-free interest rate of 3.02% and an expected life of 10 years. In the year ended December 31, 2004, the Company recorded $41,000 of compensation related to these grants to research and development expense.

During 2003, an option to purchase 15,000 shares of common stock was granted to a research consultant. The fair value of the option was estimated to be $39,000 on the date of grant using the Black-Scholes option-pricing model with the following assumptions: no dividend yield, expected volatility of 72%, risk-free interest rate of 2.93% and an expected life of 10 years. In the year ended December 31, 2003, the Company recorded $39,000 of compensation related to these grants to research and development expense.

As permitted under FAS No. 123, the Company accounts for these plans under APB Opinion No. 25. Except for compensation expense recognized for options granted to research consultants as discussed above, no compensation cost has been recognized because the exercise price equaled the market value of stock on the date of grant. Options under these plans generally vest over four years, and all options expire after ten years.

Stock Purchase Plan

Under the 1994 Employee Stock Purchase Plan, or the Stock Purchase Plan, the Company reserved 800,000 shares of common stock for issuance to employees pursuant to the Stock Purchase Plan, under which eligible employees may authorize payroll deductions of up to 10% of their base compensation (as defined) to purchase common stock at a price equal to 85% of the lower of the fair market value as of the beginning or the end of the offering period.

At the annual meeting held on June 4, 2003, the stockholders approved amendments to the Stock Purchase Plan to (i) extend the original term of the Stock Purchase Plan by an additional 10 years such that the Stock Purchase Plan will now expire in April 2014

(subject to earlier termination as described in the Stock Purchase Plan) and (ii) increase the number of shares of Common Stock reserved for issuance under the Stock Purchase Plan by 600,000 shares to a new total of 1,400,000 (collectively referred to herein as the 1994 Purchase Plan Amendments).

As of December 31, 2005, 920,754 shares have been issued to employees and there are 479,246 available for issuance under the Stock Purchase Plan. The weighted average fair market value of shares issued under the Stock Purchase Plan in 2005, 2004 and 2003 was $2.30, $3.90, and $3.02 per share, respectively.

Note 9. Agreements

During the first quarter of 2004, VIVUS initiated a Phase 2 clinical trial with avanafil, its oral PDE5 inhibitor product candidate for the treatment of erectile dysfunction. Under the terms of the 2001 Development, Licensing and Supply Agreement with Tanabe, the Company has accrued through December 31, 2005, a $2.0 million license fee obligation to Tanabe. VIVUS intends to pay this license fee in March 2006. The Company expects to make other substantial payments to Tanabe in accordance with its agreements with them. These payments are based on certain development, regulatory and sales milestones. In addition, VIVUS is required to make royalty payments on any future product sales.

In February 2004, the Company entered into exclusive licensing agreements with Acrux Limited and a subsidiary of Acrux under which it has agreed to develop and commercialize Testosterone MDTS® (metered-dose transdermal spray) and Evamist™ in the United States for various female health applications. Under the terms of the agreements, the Company agreed to pay to Acrux combined licensing fees of $3.0 million, up to $4.3 million for the achievement of certain clinical development milestones, up to $6.0 million for achieving product approval milestones, and royalties on net sales in the United States upon commercialization of each product. The Company expensed $375,000 and $3.3 million of milestone and licensing fees under the terms of the agreements in 2005 and 2004, respectively.

The Company has entered into several agreements to license patented technologies that are essential to the development and production of the Company s transurethral products for the treatment of ED. These agreements generally required milestone payments during the development period. In connection with these agreements, the Company is obligated to pay royalties on product sales covered by the license agreements (4% of United States and Canadian product sales and 3% of sales elsewhere in the world). In 2005, 2004 and 2003, the Company recorded royalty expenses, in thousands, of $556, $949 and $952, respectively, as cost of goods sold.

International sales are transacted through distributors. The distribution agreements include certain milestone payments from the distributors to the Company upon achieving established sales thresholds.

Note 10. Commitments

The Company purchased its previously leased manufacturing facilities in Lakewood, New Jersey on December 22, 2005. In January 2000, the Company entered into a seven-year lease for its corporate headquarters in Mountain View, California, which expires in January 2007. The Company intends to seek appropriate facilities to house its corporate headquarters and will enter into a long-term lease under acceptable terms.

Future minimum lease payments under operating leases are as follows (in thousands):

2006	$	735
2007		61
	$	796

Rent expense, in thousands, under operating leases totaled $1,466, $1,486 and $1,252 for the years ended December 31, 2005, 2004, and 2003, respectively.

In November 2002, the Company entered into a manufacturing agreement to purchase raw materials from a supplier beginning in 2003 and ending in 2008. The Company s remaining commitment under this agreement is to purchase a minimum total of $2.3 million of product from 2006 through 2008. In 2005, the Company purchased $765,000 of product, and in 2004 it purchased $762,000 of product from this supplier.

In January 2004, the Company entered into a manufacturing agreement to purchase raw materials from an additional supplier beginning in 2004 and ending in 2006. In February 2006, the terms of this agreement were amended. In 2004, the Company purchased $475,000 of product, and in 2005 it purchased $240,000 of product. Per the terms of the amended agreement, the Company will be required to purchase a minimum total of $1.5 million of product from 2006 through 2008.

Note 11. Income Taxes

Deferred income taxes result from differences in the recognition of expenses for tax and financial reporting purposes, as well as operating loss and tax credit carry forwards. Significant components of the Company s deferred income tax assets as of December 31 are as follows (in thousands):

	2005	2004
Deferred tax assets:		
Net operating loss carry forwards	$ 37,279	$ 26,718
Research and development credit carry forwards	6,284	6,033
Inventory reserve	1,469	1,528
Accruals and other	3,347	5,853
Depreciation	2,989	1,979
	51,368	42,111
Valuation allowance	(51,368)	(42,111)
Total	$	$

For federal and California income tax reporting purposes, respective net operating loss, or NOL, carry forwards of approximately $104.7 million and $10.8 million are available to reduce further taxable income, if any. For federal and California income tax reporting purposes, respective credit carry forwards of approximately $4.4 million and $2.9 million are available to reduce future taxable income, if any. The carry forwards, except for the California research and development credit, expire on various dates through 2025. The California research and development credits do not expire. The Internal Revenue Code of 1986, as amended, contains provisions that may limit the net operating loss and credit carry forwards available for use in any given period upon the occurrence of certain events, including a significant change in ownership interest.

A valuation allowance has been recorded for the entire deferred tax asset as a result of uncertainties regarding the realization of the asset balance due to the history of losses and the variability of operating results. The net change in the valuation allowance from December 31, 2004 to December 31, 2005 was $9.3 million. As of December 31, 2005 and 2004, the Company had no significant deferred tax liabilities.

The (benefit)/provision for income taxes attributable to continuing operations is based upon (loss)/income before (benefit)/provision for income taxes as follows, for the years ended December 31, 2005, 2004 and 2003 (in thousands):

	2005	2004	2003
Loss before income taxes:			
Domestic	$ (24,135)	$ (20,388)	$ (2,188)
International	(324)	(1,189)	1,843
Total	$ (24,459)	$ (21,577)	$ (345)

The provision/(benefit) for income taxes consists of the following components for the years ended December 31, 2005, 2004 and 2003 (in thousands):

	2005	2004	2003
Current			

Federal	$	$	$ (311)
State	18	2	(14)
Foreign	7	4	6
Total provision/(benefit) for income taxes	$ 25	$ 6	$ (319)

The (benefit)/provision for income taxes differs from the amount computed by applying the statutory federal income tax rates as follows, for the years ended December 31, 2005, 2004 and 2003:

	2005	2004	2003
(Benefit)/provision computed at federal statutory rates	(35)%	(35)%	(35)%
State income taxes, net of federal tax effect	(4)	(4)	(4)
Change in valuation allowance	39	38	39
Refund of taxes			(2)
Adjustment of income tax payable			(90)
Tax credits		1	
(Benefit)/provision for income taxes	0%	0%	(92)%

The 2003 tax benefit was based on updated estimate of net tax liabilities.

Note 12. Concentration of Customers and Suppliers

Sales to significant customers as a percentage of total revenues for the years ended December 31, 2005, 2004 and 2003 are as follows:

	2005	2004	2003
Customer A	42%	46%	23%
Customer B	23%	27%	21%
Customer C	0%	0%	18%
Customer D	13%	12%	16%
Customer E	15%	12%	11%

Customer C merged with Customer D in 2004.

Accounts receivable at December 31, 2005 and 2004 by significant customer as a percentage of the total gross accounts receivable balance are as follows:

	2005	2004
Customer A	36%	51%
Customer B	48%	36%
Customer C	0%	0%
Customer D	8%	4%
Customer E	5%	2%

Customer C merged with Customer D in 2004.

The Company did not have any suppliers making up more than 10% of operating costs.

Note 13. 401(k) Plan

All of the Company s employees are eligible to participate in the VIVUS 401(k) Plan. Employer-matching contributions for the years ended December 31, 2005, 2004 and 2003, in thousands were $270, $261 and $241, respectively. The employer-matching portion of the 401(k) plan began on July 1, 2000.

Note 14. Legal Matters

In the normal course of business, the Company receives claims and makes inquiries regarding patent infringement and other legal matters. The Company believes that it has meritorious claims and defenses and intends to pursue any such matters vigorously. The Company has received notice from a former employee seeking payment due to their termination in 2005. The Company believes the employee has no claim to additional compensation and it will seek to conclude this matter without a material impact on its financial position. The Company is not aware of any asserted or unasserted claims against it where an unfavorable resolution would have an adverse material impact on the operations or financial position of the Company.

Note 15. Related Party Transactions

Mario M. Rosati, one of the Company s directors, is also a member of Wilson Sonsini Goodrich and Rosati, Professional Corporation, which has served as the Company s outside corporate counsel since its formation and has received compensation at normal commercial rates for its services. In 2005, 2004 and 2003 the Company paid $344,000, $305,000 and $234,000, respectively, to Wilson Sonsini Goodrich and Rosati for legal services.

Note 16. Subsequent Events (Unaudited)

On January 4, 2006, the Company obtained a $5.4 million loan from Crown Bank, N.A. (Crown), secured by the land and buildings, among other assets, located at its principal manufacturing facility and a $700,000 Certificate of Deposit held by Crown. The loan is payable over a 10-year term and the interest rate will be fixed at 8.25%, which is the prime rate plus 1% at the time of funding and then will be adjusted annually to a fixed rate for the year equal to the prime rate plus 1% with a floor of 7.5%.

In January 2006, in accordance with the terms of the international supply agreement signed with Meda AB in September 2002, the Company received a $2.0 million milestone fee. The Company recorded the $2.0 million fee of unearned revenue related to this payment and this amount will be recognized as income ratably over the term of the supply agreement.

On February 21, 2006, the Company entered into the First Amendment and Waiver (the Amendment) to the Manufacture and Supply Agreement (the Original Agreement) effective December 22, 2003 with NeraPharm spol, s.r.o. Under the Amendment, the Company s minimum quantity purchase requirements were amended such that the minimum quantity of alprostadil (the Product) for calendar year 2005 will be ordered by the Company and delivered by NeraPharm on or before April 30, 2006 and the minimum quantity of Product to be ordered by the Company in 2006 shall be postponed until 2008, with such order and delivery occurring on or before December 31, 2008.

Note 17. Selected Financial Data (Unaudited)

Selected Quarterly Financial Data (in thousands)

	Quarter Ended,			
	March 31	June 30	September 30	December 31
2005				
Total revenue	$ 629	$ 1,716	$ 3,267	$ 9,042
Cost of goods sold	$ 2,090	$ 2,049	$ 2,477	$ 4,402
Net loss	$ (8,837)	$ (8,650)	$ (5,960)	$ (1,037)
Net loss per share:				
Basic and diluted	$ (0.22)	$ (0.19)	$ (0.13)	$ (0.02)
2004				
Total revenue	$ 1,942	$ 3,202	$ 4,331	$ 10,126
Cost of goods sold	$ 2,280	$ 2,324	$ 2,634	$ 4,045
Net loss	$ (10,899)	$ (4,880)	$ (4,917)	$ (887)
Net loss per share:				
Basic and diluted	$ (0.29)	$ (0.13)	$ (0.13)	$ (0.02)

FINANCIAL STATEMENT SCHEDULE

The financial statement Schedule II - VALUATION AND QUALIFYING ACCOUNTS is filed as part of the Form 10-K.

VIVUS, Inc.

SCHEDULE II - VALUATION AND QUALIFYING ACCOUNTS

(in thousands)

	Balance at Beginning of Period	Charged to Operations	Charges Utilized	Balance at End of Period
Allowance for Doubtful Accounts				
Fiscal year ended December 31, 2003	$ 145	$ (24)	$ (53)	$ 68
Fiscal year ended December 31, 2004	68	42	(6)	104
Fiscal year ended December 31, 2005	104	133	(35)	202
Inventory Reserve				
Fiscal year ended December 31, 2003	7,221	56	(1,724)(1)	5,553
Fiscal year ended December 31, 2004	5,553	158	(1,794)(2)	3,917
Fiscal year ended December 31, 2005	3,917	107	(258)(3)	3,766
Product Returns				
Fiscal year ended December 31, 2003	2,280	1,906	(1,163)	3,023
Fiscal year ended December 31, 2004	3,023	1,912	(1,724)	3,211
Fiscal year ended December 31, 2005	$ 3,211	$ 1,171	$ (1,366)	$ 3,016

(1) The Company used $1.2 million of its fully reserved inventory in production. The fully reserved inventory is charged to cost of goods sold at a zero basis when used, which has a favorable impact on gross profit.

(2) The Company used $844,000 of its fully reserved inventory in production. The fully reserved inventory is charged to cost of goods sold at a zero basis when used, which has a favorable impact on gross profit. In the fourth quarter of 2004, the Company determined that it would likely not use the fully reserved raw materials inventory in future production.

(3) The Company used $76,000 of its fully reserved component parts inventory in production. The fully reserved inventory is charged to cost of goods sold at a zero basis when used, which has a favorable impact on gross profit. In the first quarter of 2005, the Company determined that it likely would continue to use some portion of the fully reserved component parts in production.

Item 9. ***Changes in and Disagreements with Accountants on Accounting and Financial Disclosure***

None.

Item 9A. ***Controls and Procedures***

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the timelines specified in the Securities and Exchange Commission s rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can only provide reasonable assurance of achieving the desired control objectives, and in reaching a reasonable level of assurance, management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

As required by SEC Rule 13a-15(b), the Company carried out an evaluation, under the supervision and with the participation of the Company s management, including the Company s Chief Executive Officer and the Company s Chief Financial Officer, of the effectiveness of the design and operation of the Company s disclosure controls and procedures as of the end of the year covered by this report. Based on the foregoing, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level.

Management s Report on Internal Control Over Financial Reporting

Internal control over financial reporting refers to the process designed by, or under the supervision of, our Chief Executive Officer and Chief Financial Officer, and effected by our board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles, and includes those policies and procedures that:

(1) Pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets;

(2) Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorization of our management and directors; and

(3) Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisitions, use or disposition of our assets that could have a material effect on the financial statements.

Internal control over financial reporting cannot provide absolute assurance of achieving financial reporting objectives because of its inherent limitations. Internal control over financial reporting is a process that involves human diligence and compliance and is subject to lapses in judgment and breakdowns resulting from human failures. Internal control over financial reporting also can be circumvented by collusion or improper management override. Because of such limitations, there is a risk that material misstatements may not be prevented or detected on a timely basis by internal control over financial reporting. However, these inherent limitations are known features of the financial reporting process. Therefore, it is possible to design into the process safeguards to reduce, though not eliminate, this risk. Management is responsible for establishing and maintaining adequate internal control over financial reporting for the company.

Management has used the framework set forth in the report entitled *Internal Control-Integrated Framework* published by the Committee of Sponsoring Organizations of the Treadway Commission, known as COSO, to evaluate the effectiveness of the Company s internal control over financial reporting. Based on this assessment, management has concluded that our internal control over financial reporting was effective as of December 31, 2005. Odenberg Ullakko Muranishi & Co. LLP, the independent registered public accounting firm that audited the consolidated financial statements included in the Annual Report on Form 10-K, has issued an attestation report on management s assessment of the effectiveness of our internal control over financial reporting as of December 31, 2005. This report, which expresses an unqualified opinion on management s assessment of and the effectiveness of our internal controls over financial reporting as of December 31, 2005, is included herein.

There has been no change in our internal controls over financial reporting during our most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal controls over financial reporting.

Item 9B. ***Other Information***

None.

PART III

Item 10. ***Executive Officers and Directors of the Registrant***

The information required by this item is hereby incorporated by reference from the information under the captions Election of Directors and Executive Officers contained in the Company s definitive Proxy Statement, to be filed with the Securities and Exchange Commission no later than 120 days from the end of the Company s last fiscal year in connection with the solicitation of proxies for its 2005 Annual Meeting of Stockholders. The information required by Section 16(a) is incorporated by reference from the information under the caption Compliance with Section 16(a) of the Securities Exchange Act of 1934 in the Proxy Statement.

The Company has adopted a code of ethics that applies to its Chief Executive Officer, Chief Financial Officer, and to all of its other officers, directors, employees and agents. The code of ethics is available at the Corporate Governance section of the Investor Relations page on the Company s website at *www.vivus.com*. The Company intends to disclose future amendments to, or waivers from, certain provision of its code of ethics on the above website within five business days following the date of such amendment or waiver.

Item 11. ***Executive Compensation***

The information required by this item is incorporated by reference from the information under the caption Executive Officer Compensation in the Company s Proxy Statement referred to in Item 10 above.

Item 12. ***Security Ownership of Certain Beneficial Owners and Management***

The information required by this item is incorporated by reference from the information under the caption Security Ownership of Certain Beneficial Owners and Management in the Company s Proxy Statement referred to in Item 10 above.

Item 13. ***Certain Relationships and Related Transactions***

The information required by this item is incorporated by reference from the information under the caption Certain Relationships and Related Transactions in the Company s Proxy Statement referred to in Item 10 above.

Item 14. ***Principal Accounting Fees and Services***

The information required by this item is incorporated by reference from the information under the caption Principal Accounting Fees and Services in the Company s Proxy Statement referred to in Item 10 above.

PART IV

Item 15. ***Exhibits and Financial Statement Schedules***

(a) Documents filed as part of this report.

1. Financial Statements

The following Financial Statements of VIVUS, Inc. and Reports of Independent Registered Public Accounting Firms have been filed as part of this Form 10-K. See index to Financial Statements under Item 8, above:

Index to Consolidated Financial Statements

2. Financial Statement Schedules

The following financial statement schedule of VIVUS, Inc. as set forth on page 62 is filed as part of this Form 10-K and should be read in conjunction with the Financial Statements of VIVUS, Inc. incorporated by reference herein:

All other schedules are omitted because they are not applicable or the required information is shown in the Financial Statements or the notes thereto.

3. Exhibits

The list of Exhibits required by Item 601 of Regulation S-K. See part (b) below.

(b). Exhibits

Exhibit Number	Description
3.2(4)	Amended and Restated Certificate of Incorporation of the Registrant
3.3(3)	Bylaws of the Registrant, as amended
3.4(5)	Certificate of Designation of Rights, Preferences and Privileges of Series A Participating Preferred Stock
4.1(4)	Specimen Common Stock Certificate of the Registrant
4.5(5)	Second Amended and Restated Preferred Shares Rights Agreement, dated as of April 15, 1997 by and between the Registrant and Harris Trust Company of California, including the form of Certificate of Determination, the form of Rights Certificate and the Summary of Rights attached thereto as Exhibits A, B, and C, respectively
10.1(1)	Assignment Agreement by and between Alza Corporation and the Registrant dated December 31, 1993
10.2(1)	Memorandum of Understanding by and between Ortho Pharmaceutical Corporation and the Registrant dated February 25, 1992
10.3(1)	Assignment Agreement by and between Ortho Pharmaceutical Corporation and the Registrant dated June 9, 1992
10.4(1)	License Agreement by and between Gene A. Voss, MD, Allen C. Eichler, MD, and the Registrant dated December 28, 1992
10.5A(1)	License Agreement by and between Ortho Pharmaceutical Corporation and Kjell Holmquist AB dated June 23, 1989
10.5B(1)	Amendment by and between Kjell Holmquist AB and the Registrant dated July 3, 1992
10.5C(1)	Amendment by and between Kjell Holmquist AB and the Registrant dated April 22, 1992
10.5D(1)	Stock Purchase Agreement by and between Kjell Holmquist AB and the Registrant dated April 22, 1992

Exhibit Number	Description
10.6A(1)	License Agreement by and between Amsu, Ltd., and Ortho Pharmaceutical Corporation dated June 23, 1989
10.6B(1)	Amendment by and between Amsu, Ltd., and the Registrant dated July 3, 1992
10.6C(1)	Amendment by and between Amsu, Ltd., and the Registrant dated April 22, 1992
10.6D(1)	Stock Purchase Agreement by and between Amsu, Ltd., and the Registrant dated July 10, 1992
10.11(3)	Form of Indemnification Agreement by and among the Registrant and the Directors and Officers of the Registrant
10.12(2)	1991 Incentive Stock Plan and Form of Agreement, as amended
10.13(1)	1994 Director Option Plan and Form of Agreement
10.14(1)	Form of 1994 Employee Stock Purchase Plan and Form of Subscription Agreement
10.17(1)	Letter Agreement between the Registrant and Leland F. Wilson dated June 14, 1991 concerning severance pay
10.28(4)	Lease Agreement made as of January 1, 1997 between the Registrant and Airport Associates
10.29(4)	Lease Amendment No. 1 as of February 15, 1997 between Registrant and Airport Associates
10.29A(6)	Lease Amendment No. 2 dated July 24, 1997 by and between the Registrant and Airport Associates
10.29B(6)	Lease Amendment No. 3 dated July 24, 1997 by and between the Registrant and Airport Associates
10.36(7)	Form of Change of Control Agreements dated July 8, 1998 by and between the Registrant and certain Executive Officers of the Company
10.39(8)	Sublease agreement between KVO Public Relations, Inc. and the Registrant dated December 21, 1999
10.41(9)	Distribution and Supply Agreement made as of November 20, 2000 between the Registrant and Paladin Labs, Inc.
10.42(9)	Development, License and Supply Agreement made as of January 22, 2001 between the Registrant and Tanabe Seiyaku Co., Ltd.
10.42A(14)	Amendment One to Agreement, dated January 9, 2004 between the Registrant and Tanabe Seiyaku Co., Ltd.
10.43(10)	Settlement and Modification Agreement made as of July 12, 2001 between ASIVI, LLC, AndroSolutions, Inc., Gary W. Neal and the Registrant
10.44(11)	2001 Stock Option Plan and Form of Agreement
10.45(12)	Supply Agreement made as of September 3, 2002 between the Registrant and Meda AB
10.46(13)	Amendment Three, dated November 21, 2002 by and between the Registrant and CHINOIN Pharmaceutical and Chemical Works, Ltd.
10.47(13)	Lease Amendment No. 4 and Settlement Agreement dated October 25, 2000 by and between the Registrant and Airport Associates
10.48(13)	Exclusive Distribution Agreement effective as of October 1, 2002 between the Registrant and Cord Logistics, Inc.
10.49(13)	Distribution and Supply Agreement effective as of February 18, 2003 between the Registrant and Meda AB
10.50(14)	Testosterone Development and Commercialization Agreement effective as of February 7, 2004 between the Registrant, Fempharm Pty Ltd. and Acrux DDS Pty Ltd.
10.51(14)	Estradiol Development and Commercialization Agreement effective as of February 12, 2004 between the Registrant, Fempharm Pty Ltd. and Acrux DDS Pty Ltd.
10.52(14)	Note Purchase Agreement dated January 8, 2004 between the Registrant and Tanabe Holding America, Inc.
10.53(14)	Manufacture and Supply Agreement dated December 22, 2003 between the Registrant and NeraPharm spol., s.r.o.
10.54(15)	Amendment One dated October 11, 2004 to License and Supply Agreement made between the Registrant and Paladin Labs, Inc.
10.55(16)	Agreement for Sale of Real Estate dated November 15, 2005 by and between the Registrant and 735 Airport Road, L.L.C.
10.56(16)	Agreement for Sale of Real Estate dated November 15, 2005 by and between the Registrant and 745 Airport Road, L.L.C.
10.57(17)	Term Loan Agreement dated January 4, 2006 by and between the Registrant and Vivus Real Estate LLC and Crown Bank, N.A.
10.58(17)	Commercial Mortgage Note dated January 4, 2006 by and between the Registrant and Vivus Real Estate LLC and Crown Bank, N.A.
10.59(17)	Mortgage and Security Agreement dated January 4, 2006 by and between Vivus Real Estate LLC and Crown Bank, N. A.

Exhibit Number	Description
21.2	Subsidiaries of the Registrant
23.1	Consent of ODENBERG, ULLAKKO, MURANISHI & Co. LLP, Independent Registered Public Accounting Firm
23.2	Consent of KPMG LLP, Independent Registered Public Accounting Firm
31.1	Certification of Chief Executive Officer, dated March 13, 2006, pursuant to Rules 13a-14 and 15d-14 promulgated under the Securities Exchange Act of 1934, as amended
31.2	Certification of Chief Financial Officer, dated March 13, 2006, pursuant to Rules 13a-14 and 15d-14 promulgated under the Securities Exchange Act of 1934, as amended
32	Certification of Chief Executive Officer and Chief Financial Officer pursuant to Section 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

Confidential treatment granted.

(1) Incorporated by reference to the same numbered exhibit filed with the Registrant s Registration Statement on Form S-1 No. 33-75698, as amended.

(2) Incorporated by reference to the same numbered exhibit filed with the Registrant s Registration Statement on Form S-1 No. 33-90390, as amended.

(3) Incorporated by reference to the same numbered exhibit filed with the Registrant s Form 8-B filed with the Commission on June 25, 1996.

(4) Incorporated by reference to the same numbered exhibit filed with the Registrant s Annual Report on Form 10-K for the year ended December 31, 1996, as amended.

(5) Incorporated by reference to exhibit 99.1 filed with Registrant s Amendment Number 2 to the Registration Statement of Form 8-A (File No. 0-23490) filed with the Commission on April 23, 1997.

(6) Incorporated by reference to the same numbered exhibit filed with the Registrant s Quarterly Report on Form 10-Q for the quarter ended September 30, 1997.

(7) Incorporated by reference to the same numbered exhibit filed with the Registrant s Annual Report on Form 10-K for the year ended December 31, 1998.

(8) Incorporated by reference to the same numbered exhibit filed with the Registrant s Annual Report on Form 10-K for the year ended December 31, 1999.

(9) Incorporated by reference to the same numbered exhibit filed with the Registrant s Annual Report on Form 10-K for the year ended December 31, 2000.

(10) Incorporated by reference to the same numbered exhibit filed with the Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2001.

(11) Incorporated by reference to the same numbered exhibit filed with the Registrant s Registration Statement on Form S-8 filed with the Commission on November 15, 2001.

(12) Incorporated by reference to the same numbered exhibit filed with the Registrant s Quarterly Report on Form 10-Q for the quarter ended September 30, 2002.

(13) Incorporated by reference to the same numbered exhibit filed with the Registrant s Annual Report on Form 10-K for the year ended December 31, 2002.

(14) Incorporated by reference to the same numbered exhibit filed with the Registrant s Annual Report on Form 10-Q for the quarter ended March 31, 2004.

(15) Incorporated by reference to the same numbered exhibit filed with the Registrant s Annual Report on Form 10-K for the year ended December 31, 2004.

(16) Incorporated by reference to the same numbered exhibit filed with the Registrant s Form 8-K filed with the Commission on December 23, 2005.

(17) Incorporated by reference to the same numbered exhibit filed with the Registrant s Form 8-K filed with the Commission on January 6, 2006.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized:

VIVUS, INC.,
a Delaware Corporation

By: /s/ TIMOTHY E. MORRIS
Timothy E. Morris
Vice President, Finance and Chief Financial Officer
(Principal Financial and Accounting Officer)

Date: March 13, 2006

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints each of Leland F. Wilson and Timothy E. Morris as his attorney-in-fact for him, in any and all capacities, to sign each amendment to this Report on Form 10-K, and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and confirming all that said attorney-in-fact or his substitute or substitutes may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this Report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated:

Signature	Title	Date
/s/ LELAND F. WILSON Leland F. Wilson	President, Chief Executive Officer (Principal Executive Officer) and Director	March 13, 2006
/s/ VIRGIL A. PLACE Virgil A. Place	Chairman of the Board and Chief Scientific Officer and Director	March 13, 2006
/s/ TIMOTHY E. MORRIS Timothy E. Morris	Vice President of Finance and Chief Financial Officer (Principal Financial and Accounting Officer)	March 13, 2006
/s/ GRAHAM STRACHAN Graham Strachan	Director	March 13, 2006
/s/ MARIO M. ROSATI Mario M. Rosati	Director	March 13, 2006
/s/ MARK B. LOGAN Mark B. Logan	Director	March 13, 2006
/s/ LINDA M. DAIRIKI SHORTLIFFE, M.D. Linda M. Dairiki Shortliffe, M.D.	Director	March 13, 2006

VIVUS, INC.

REPORT ON FORM 10-K FOR

THE YEAR ENDED DECEMBER 31, 2005

INDEX TO EXHIBITS

Exhibit Number	Description
3.2(4)	Amended and Restated Certificate of Incorporation of the Registrant
3.3(3)	Bylaws of the Registrant, as amended
3.4(5)	Certificate of Designation of Rights, Preferences and Privileges of Series A Participating Preferred Stock
4.1(4)	Specimen Common Stock Certificate of the Registrant
4.5(5)	Second Amended and Restated Preferred Shares Rights Agreement, dated as of April 15, 1997 by and between the Registrant and Harris Trust Company of California, including the form of Certificate of Determination, the form of Rights Certificate and the Summary of Rights attached thereto as Exhibits A, B, and C, respectively
10.1(1)	Assignment Agreement by and between Alza Corporation and the Registrant dated December 31, 1993
10.2(1)	Memorandum of Understanding by and between Ortho Pharmaceutical Corporation and the Registrant dated February 25, 1992
10.3(1)	Assignment Agreement by and between Ortho Pharmaceutical Corporation and the Registrant dated June 9, 1992
10.4(1)	License Agreement by and between Gene A. Voss, MD, Allen C. Eichler, MD, and the Registrant dated December 28, 1992
10.5A(1)	License Agreement by and between Ortho Pharmaceutical Corporation and Kjell Holmquist AB dated June 23, 1989
10.5B(1)	Amendment by and between Kjell Holmquist AB and the Registrant dated July 3, 1992
10.5C(1)	Amendment by and between Kjell Holmquist AB and the Registrant dated April 22, 1992
10.5D(1)	Stock Purchase Agreement by and between Kjell Holmquist AB and the Registrant dated April 22, 1992
10.6A(1)	License Agreement by and between Amsu, Ltd., and Ortho Pharmaceutical Corporation dated June 23, 1989
10.6B(1)	Amendment by and between Amsu, Ltd., and the Registrant dated July 3, 1992
10.6C(1)	Amendment by and between Amsu, Ltd., and the Registrant dated April 22, 1992
10.6D(1)	Stock Purchase Agreement by and between Amsu, Ltd., and the Registrant dated July 10, 1992
10.11(3)	Form of Indemnification Agreement by and among the Registrant and the Directors and Officers of the Registrant
10.12(2)	1991 Incentive Stock Plan and Form of Agreement, as amended
10.13(1)	1994 Director Option Plan and Form of Agreement
10.14(1)	Form of 1994 Employee Stock Purchase Plan and Form of Subscription Agreement
10.17(1)	Letter Agreement between the Registrant and Leland F. Wilson dated June 14, 1991 concerning severance pay
10.28(4)	Lease Agreement made as of January 1, 1997 between the Registrant and Airport Associates
10.29(4)	Lease Amendment No. 1 as of February 15, 1997 between the Registrant and Airport Associates
10.29A(6)	Lease Amendment No. 2 dated July 24, 1997 by and between the Registrant and Airport Associates
10.29B(6)	Lease Amendment No. 3 dated July 24, 1997 by and between the Registrant and Airport Associates
10.36(7)	Form of Change of Control Agreements, dated July 8, 1998 by and between the Registrant and certain Executive Officers of the Company
10.39(8)	Sublease agreement between KVO Public Relations, Inc. and the Registrant dated December 21, 1999
10.41(9)	Distribution and Supply Agreement made as of November 20, 2000 between the Registrant and Paladin Labs, Inc.
10.42(9)	Development, License and Supply Agreement made as of January 22, 2001 between the Registrant and Tanabe Seiyaku Co., Ltd.
10.42A(14)	Amendment One to Agreement, dated January 9, 2004 between the Registrant and Tanabe Seiyaku Co., Ltd.
10.43(10)	Settlement and Modification Agreement made as of July 12, 2001 between ASIVI, LLC, AndroSolutions, Inc., Gary W. Neal and the Registrant
10.44(11)	2001 Stock Option Plan and Form of Agreement

10.45(12) Supply Agreement made as of September 3, 2002 between the Registrant and Meda AB

Exhibit Number	Description
10.46(13)	Amendment Three, dated November 21, 2002 by and between the Registrant and CHINOIN Pharmaceutical and Chemical Works, Ltd.
10.47(13)	Lease Amendment No. 4 and Settlement Agreement dated October 25, 2000 by and between the Registrant and Airport Associates
10.48(13)	Exclusive Distribution Agreement effective as of October 1, 2002 between the Registrant and Cord Logistics, Inc.
10.49(13)	Distribution and Supply Agreement effective as of February 18, 2003 between the Registrant and Meda AB
10.50(14)	Testosterone Development and Commercialization Agreement effective as of February 7, 2004 between the Registrant, Fempharm Pty Ltd. and Acrux DDS Pty Ltd.
10.51(14)	Estradiol Development and Commercialization Agreement effective as of February 12, 2004 between the Registrant, Fempharm Pty Ltd. and Acrux DDS Pty Ltd.
10.52(14)	Note Purchase Agreement dated January 8, 2004 between the Registrant and Tanabe Holding America, Inc.
10.53(14)	Manufacture and Supply Agreement dated December 22, 2003 between the Registrant and NeraPharm spol., s.r.o.
10.54(15)	Amendment One dated October 11, 2004 to License and Supply Agreement made between the Registrant and Paladin Labs, Inc.
10.55(16)	Agreement for Sale of Real Estate dated November 15, 2005 by and between the Registrant and 735 Airport Road, L.L.C.
10.56(16)	Agreement for Sale of Real Estate dated November 15, 2005 by and between the Registrant and 745 Airport Road, L.L.C.
10.57(17)	Term Loan Agreement dated January 4, 2006 by and between the Registrant and Vivus Real Estate LLC and Crown Bank, N.A.
10.58(17)	Commercial Mortgage Note dated January 4, 2006 by and between the Registrant and Vivus Real Estate LLC and Crown Bank, N.A.
10.59(17)	Mortgage and Security Agreement dated January 4, 2006 by and between Vivus Real Estate LLC and Crown Bank, N. A.
21.2	Subsidiaries of the Registrant
23.1	Consent of ODENBERG, ULLAKKO, MURANISHI & Co. LLP, Independent Registered Public Accounting Firm
23.2	Consent of KPMG LLP, Independent Registered Public Accounting Firm
31.1	Certification of Chief Executive Officer, dated March 13, 2006, pursuant to Rules 13a-14 and 15d-14 promulgated under the Securities Exchange Act of 1934, as amended
31.2	Certification of Chief Financial Officer, dated March 13, 2006, pursuant to Rules 13a-14 and 15d-14 promulgated under the Securities Exchange Act of 1934, as amended
32	Certification of Chief Executive Officer and Chief Financial Officer pursuant to Section 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

Confidential treatment granted.

(1) Incorporated by reference to the same numbered exhibit filed with the Registrant s Registration Statement on Form S-1 No. 33-75698, as amended.

(2) Incorporated by reference to the same numbered exhibit filed with the Registrant s Registration Statement on Form S-1 No. 33-90390, as amended.

(3) Incorporated by reference to the same numbered exhibit filed with the Registrant s Form 8-B filed with the Commission on June 25, 1996.

(4) Incorporated by reference to the same numbered exhibit filed with the Registrant s Annual Report on Form 10-K for the year ended December 31, 1996, as amended.

(5) Incorporated by reference to exhibit 99.1 filed with Registrant s Amendment Number 2 to the Registration Statement of Form 8-A (File No. 0-23490) filed with the Commission on April 23, 1997.

(6) Incorporated by reference to the same numbered exhibit filed with the Registrant s Quarterly Report on Form 10-Q for the quarter ended September 30, 1997.

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(7) Incorporated by reference to the same numbered exhibit filed with the Registrant s Annual Report on Form 10-K for the year ended December 31, 1998.

(8) Incorporated by reference to the same numbered exhibit filed with the Registrant s Annual Report on Form 10-K for the year ended December 31, 1999.

(9) Incorporated by reference to the same numbered exhibit filed with the Registrant s Annual Report on Form 10-K for the year ended December 31, 2000.

(10) Incorporated by reference to the same numbered exhibit filed with the Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2001.

(11) Incorporated by reference to the same numbered exhibit filed with the Registrant s Registration Statement on Form S-8 filed with the Commission on November 15, 2001.

(12) Incorporated by reference to the same numbered exhibit filed with the Registrant s Quarterly Report on Form 10-Q for the quarter ended September 30, 2002.

(13) Incorporated by reference to the same numbered exhibit filed with the Registrant s Annual Report on Form 10-K for the year ended December 31, 2002.

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